

**Does a 'baby-led' approach to complementary feeding alter
the risk of choking and growth faltering in infants aged 0-12
months?**

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Abstract

Background: Although baby-led approaches to complementary feeding such as Baby-Led Weaning (BLW) are growing in popularity, research exploring the safety and efficacy of these approaches is sparse. Concerns have also been expressed regarding the potential for BLW to increase the risk of choking, growth faltering and iron deficiency. The Baby-Led Introduction to Solids (BLISS) randomised controlled trial investigated whether a form of BLW, modified to address these concerns, was a suitable way to introduce solids to infants.

Aim: To investigate whether the BLISS approach to complementary feeding alters the risk of food-related choking and growth faltering among infants aged 0-12 months.

Methods: Dunedin families (n=206) were randomly allocated to a Control or intervention (BLISS) group. Control families (n=101) received the standard government funded 'Well Child' health service. BLISS families (n=105) received Well Child care plus at least 8 parent contacts for advice and support on following the BLISS approach.

Data on the frequency of choking and gagging, the characteristics of choking events, and the impact of adherence to a baby-led approach to infant feeding were collected by questionnaires when infants were 6, 7, 8, 9 and 12 months of age. Choking and gagging frequencies were also assessed by daily calendars at 6 and 8 months. Data on infant exposure to foods thought to pose a choking risk were obtained using three-day weighed diet records at 7 and 12 months. Parental feeding practices were evaluated by questionnaires at 7, 8, 9 and 12 months.

Infant growth was determined from repeated anthropometric measurements (infant weight at 6, 7, 8, 9 and 12 months, and length at 6 and 12 months). Growth was checked against five "growth triggers" to ensure the early identification of infants at potential risk. Growth faltering was defined as a weight deceleration of >1.34 of a weight-for-age z-score (using the World Health Organization Child Growth Standards) between 6 and 9 months.

Results: Overall, 35% of infants choked at least once between 6 and 8 months of age but there were no significant group differences in the number of choking events at any time point (all $p>0.20$). BLISS infants gagged more frequently than Controls at 6 months (RR 1.56, 95% CI 1.13 to 2.17), but less frequently than Controls at 8 months (RR 0.60, 95% CI 0.42 to 0.87). At 7 and 12 months of age, 52% and 94% of infants respectively were offered food thought to pose a choking risk during weighed diet recording, although no statistically significant group differences were observed at either age (all $p>0.30$). Consistently safe parental feeding practices were often lacking in both groups, particularly at 12 months when only 44% of Control and 65% of BLISS infants always had an adult sitting with them while they ate.

Although 32 infants (16 Control, 16 BLISS) met at least one growth trigger between 6 and 12 months, only 3 (2 BLISS, 1 Control) were potentially serious enough to be referred to the study paediatrician. However, growth improved in all three infants and no child met the criterion for growth faltering.

Conclusions: Infants following the BLISS approach to complementary feeding were no more likely to choke or experience growth faltering than Control infants, although it is acknowledged that this was a relatively small study.

Keywords: infants, complementary feeding, solids, baby-led weaning, choking, gagging, growth faltering, failure to thrive

Preface

This MSc project was part of the Baby-Led Introduction to Solids (BLISS) study, which was a randomised controlled trial which began in 2012 and was completed in 2016. It was jointly conducted by the Department of Human Nutrition and the Department of Medicine at the University of Otago in Dunedin, New Zealand.

Dr Anne-Louise Heath and Associate Professor Rachael Taylor were the Co-Principal Investigators for the BLISS study. They were responsible for the design and outline of this MSc project, and for the supervision of this thesis. Associate Professor Sheila Williams was the biostatistician for the BLISS study and conducted the inferential statistical analyses for this thesis. The BLISS study paediatricians, Dr Ben Wheeler and Professor Barry Taylor, provided expert input and ongoing support and advice in the areas of growth faltering and food-related choking in infants. Speech and language therapists Lisa Gallacher and Siobhan McKinlay from Community Assessment and Rehabilitation Associates in Dunedin provided expert input into the design of the BLISS intervention and the identification of foods posing a choking risk to infants.

The focus of this thesis was to investigate the impact of the BLISS approach to complementary feeding on the risk of growth faltering and choking in infants aged 0 to 12 months. The Candidate was the primary researcher for this project and was responsible for the following:

- Co-ordinating some study participants, including the booking of infant measurement appointments and the delivery and collection of study materials to and from participants
- Conducting approximately one-quarter (n=223) of all infant measurement visits at 6, 7, 8, 9 and 12 months of age, including the collection of anthropometric measurements and the administration of questionnaires, calendars and weighed diet records

- Manually checking all electronic data entry against hardcopy questionnaires (n=720) from the 6, 7, 8 and 9 month measurement visits
- Designing the approach used to identify foods which were thought to pose a choking risk to infants
- Comparing the foods consumed by infants on each of the 471 and 418 days of weighed diet recording which were collected at 7 and 12 months respectively, with those described on the list of foods which were thought to pose a choking risk to infants
- Conducting the descriptive statistical analyses presented in this thesis
- Contributing to fortnightly BLISS meetings during the MSc period

The Candidate wrote the first draft of the following paper (and is currently drafting a rebuttal for the journal *Pediatrics*):

Fangupo LJ, Heath A-LM, Williams SM, Erickson LW, Morison BJ, Fleming EA et al. Impact of a baby-led approach to introducing solids on the risk of choking: the BLISS randomised trial.

The Candidate also contributed to the following paper which is about to be submitted:

Taylor RW, Williams SM, Fangupo LJ, Wheeler BJ, Taylor BJ, Daniels L et al. Baby-led and conventional approaches to complementary feeding for obesity prevention: a randomised controlled trial.

The Candidate also contributed to the following paper:

Morison BJ, Taylor RW, Haszard JJ, Schramm CJ, Erickson LW, Fangupo LJ et al. How different are baby-led weaning and conventional complementary feeding?
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List of Abbreviations

AAP	American Academy of Pediatrics
BLISS	Baby-Led Introduction to Solids
BLW	Baby-Led Weaning
BMI	Body Mass Index
CDC	Centers for Disease Control
CPR	Cardiopulmonary resuscitation
GP	General Practitioner
IBCLC	International Board Certified Lactation Consultant
IQ	Intelligence Quotient
LMC	Lead Maternity Carer
MDiet	Master of Dietetics
MGRS	Multicentre Growth Reference Study
MOH	Ministry of Health
MSc	Master of Science
NCHS	National Centre for Health Statistics
NZ	New Zealand
NZGC	New Zealand Growth Charts
NZ MOH	New Zealand Ministry of Health
NZDep13	New Zealand Deprivation (Index) 2013
NZ-WHO	New Zealand-World Health Organisation
OR	Odds Ratio
PhD	Doctor of Philosophy
POI	Prevention of Overweight in Infancy
RR	Relative Risk
SD	Standard Deviation
TSF	Traditional Spoon Feeding
UK	United Kingdom
UK-WHO	United Kingdom-World Health Organisation
USA	United States of America
WDR	Weighed Diet Record

WHO	World Health Organization
WHO-CGS	World Health Organization-Child Growth Standards

1. Introduction

Internationally, most infant feeding guidelines suggest that when the complementary feeding period begins at 6 months of age, infants should first be offered puréed foods (which generally need to be spoon-fed to the infant by an adult), followed by mashed, chopped and finger foods, in a gradual progression which takes several months, so that infants are consuming some family foods by their first birthday¹⁻⁴. Such practices are described as 'conventional complementary feeding methods' in this thesis.

In recent years, alternative 'baby-led' approaches to infant feeding, such as Baby-Led Weaning (BLW), which was described in detail by Gill Rapley and Tracy Murkett in their 2008 book 'Baby-Led Weaning'⁵, have grown in popularity⁶⁻⁸. They are characterised by the infant feeding themselves graspable pieces of whole food from the very beginning of the complementary feeding period. It is usually intended that infants following these approaches feed themselves *all* of their food in this manner, leaving the spoon-feeding and puréed foods which are characteristic of conventional complementary feeding methods obsolete^{5,6}. Baby-led approaches have a number of proposed advantages which are of interest to parents, health professionals and policy makers alike^{5,9}. These include better energy self-regulation (ability to eat in response to appetite), a lower risk of obesity, improved diet quality, more highly developed motor skills in infants, and more desirable feeding practices among parents⁹. Furthermore, Rapley and Murkett have promoted BLW as 'natural' and 'logical' as well as being easier, less complicated, and cheaper than conventional complementary feeding methods⁵. However, potential disadvantages of baby-led approaches have also been identified, with concerns about choking, growth faltering and iron deficiency in infants particularly prominent in the literature^{6,9-11}.

Only limited research into baby-led approaches has been completed to date; notably, at present there are no published results of randomised controlled trials investigating the safety and efficacy of these methods⁹. Because of their possible disadvantages, and the dearth of high quality research, baby-led approaches are not currently recommended for population health in New Zealand¹². However, research does indicate that many New

Zealand parents are choosing to follow baby-led approaches with their infants^{11,13}. Because of the lack of scientific support for such approaches, these parents must rely on books, websites, social media and other parents for information, support and guidance^{11,13}. As a result, their infants are potentially at risk of being supplied with foods which are unsafe or unhealthy^{11,14}. There is therefore an urgent need for a randomised controlled trial to provide the first high-quality evidence about the safety (or otherwise) of baby-led approaches to infant feeding⁹.

The Baby-Led Introduction to Solids (BLISS) randomised controlled trial aimed to determine whether a modified version of BLW (labelled “BLISS”) could prevent the development of overweight in infants in the first two years of life⁹. Important secondary outcomes of the study included whether the approach was associated with an increased risk of iron deficiency, choking or growth faltering in infants⁹. The primary study outcome will be reported by the principal investigators of the BLISS study, and a PhD candidate is responsible for investigating the risk of iron deficiency. The MSc Candidate is responsible for investigating the risk of choking and growth faltering in infants following the BLISS approach, compared to infants following conventional complementary feeding methods. The two aims of this MSc thesis are therefore:

1. To determine whether the BLISS approach to complementary feeding alters the risk of choking in infants aged 0-12 months
2. To determine whether the BLISS approach to complementary feeding alters the risk of growth faltering in infants aged 0-12 months.

2. Literature Review

2.1. Search strategies and aims

Literature searches were conducted between June 2015 and January 2016 using the search databases Ovid MEDLINE (R) (1946 to Present with Daily Update), Web of Science, and Google Scholar. Search strategies and key terms are outlined in **Table 2.1**. Only articles published in English were considered. Searches focused on primarily on findings in infants (0-12 months of age) but were extended to include children up to 14 years of age in areas where insufficient studies in infants were available. The reference lists of relevant articles were scrutinized to identify further important publications, and the World Wide Web was used to access current information from the New Zealand Ministry of Health (NZ MOH), the World Health Organization (WHO), The Order of St John, and various BLW websites and forums.

The aims of this literature review were to:

1. compare the key features of the BLW approach with current recommendations for the complementary feeding period
2. evaluate current knowledge about two possible disadvantages of baby-led approaches to infant feeding: choking and growth faltering.

Table 2.1 Terms used to identify studies in this review¹

Search terms used for Section 2.2: The complementary feeding period

1. complementary
 2. infant/infants
 3. feeding
 - 4. baby-led weaning**
 5. breastfeeding
 6. New Zealand
 7. World Health Organization
 8. guidelines
 9. recommendations
-

10. (1) AND (2) AND (3)

11. (10) AND (8) OR (9)

12. (2) AND (3) AND (6) OR (7)

13. (5) AND (8) OR (9)

Search terms used for Section 2.3: Choking

1. choking

2. gagging

3. foreign body inhalation

4. infant/infants

5. children

6. food-related

7. prevention

8. consequences

9. first aid

10. baby-led weaning

11. (1) OR (3) AND (4) OR (5)

12. (1) AND (4) AND (6)

13. (1) AND (7) AND (4) OR (5)

14. (1) AND (8)

15. (1) OR (2) AND (9)

16. (1) OR (2) AND (10)

Search terms used for Section 2.4: Growth faltering

1. growth faltering

2. failure to thrive

3. infant/infants

4. children

5. growth standards

6. growth references

7. anthropometry

8. New Zealand

9. World Health Organization

10. management

11. (1) OR (2) AND (3) OR (4)

12. (3) OR (4) AND (5) OR (6)

13. (3) OR (4) AND (7)

14. (5) OR (6) AND (8) OR (9)

15. (1) OR (2) AND (10)

¹ Items highlighted in bold text were terminally searched.

2.2 Complementary feeding

2.2.1 Background

Complementary feeding is described by the WHO as the process which starts when breast milk alone is no longer sufficient to meet the nutritional requirements of infants, so other foods and liquids are required in addition to breast milk^{4,15}. The WHO's target age range for complementary feeding is 6-24 months, although it is recognised that breastfeeding may continue beyond 2 years of age^{4,15}. Prior to the beginning of the complementary feeding period at 6 months (180 day) of age^{4,15}, exclusive breastfeeding whereby the infant receives only breast milk (either directly from the breast or expressed), and no other liquids or solid foods (with the exception of prescribed medications) is recommended¹⁶. These WHO recommendations were last updated in 2002¹⁶ and have since been adopted by many countries worldwide^{2,17} including New Zealand¹. Prior to 2002, exclusive breastfeeding was recommended until 4-6 months of age, at which time complementary foods were to be introduced¹⁶. While the change in recommendations caused considerable debate about the optimal duration of exclusive breastfeeding and therefore the age of introduction of complementary foods¹⁸⁻¹⁹, on a population basis, exclusive breastfeeding to six months of age has been found to be nutritionally adequate and to confer benefits on both the infant and the mother with no adverse effects on infant growth^{4,20}. From six months onwards it becomes difficult to meet the nutrient requirements for optimal infant growth from breast milk alone. In particular, stores of iron and zinc, of which breast milk is a poor source, are likely to be depleted by 6 months and must be supplied by complementary food²¹.

Furthermore, most 6 month old infants are developmentally ready for other foods, with their digestive and renal function, and gross and fine oral motor skills, having matured considerably since birth²²⁻²³.

2.2.2 Conventional complementary feeding methods

In conventional complementary feeding methods, infants' first foods are smooth purées¹, which are usually spoon-fed to the infant by a parent in small amounts. The NZ MOH suggests iron-fortified baby cereal and cooked, puréed meat, vegetables and fruit as examples of appropriate foods for 6 to 7 month old infants¹. Over time, the texture, variety, amount and flavour of the foods provided should be gradually increased, with milk feeds being offered before complementary foods until 8 to 9 months of age¹. In terms of texture, a progression from puréed to mashed (at 7 to 8 months) then chopped (at 8 to 12 months) foods is recommended, and it is expected that by 12 months of age the infant will be eating some family foods (provided that these are items which are appropriate for infants)¹. Although some guidelines recommend that finger foods, such as soft pieces of fruit, steamed vegetables, and bread, can be offered alongside puréed and mashed foods from 6 months of age^{1,24-25}, in reality many infants will not be routinely offered finger foods until they are ≥ 8 months old²⁶.

Responsive feeding is encouraged throughout the complementary feeding period¹. The WHO recommendations include suggestions that parents pay attention to infant hunger and satiety cues, feed slowly and patiently, encourage (but not force) infants to eat, and remember that mealtimes are periods of learning and love, to be undertaken in safe, positive feeding environments⁴.

2.2.3 The baby-led weaning method

In the first months of life, the BLW approach⁵ aligns with the WHO recommendations:^{4,16} exclusive breastfeeding is recommended (although it is acknowledged that some infants will be formula fed) with solid foods only becoming necessary when infants reach 6 months of age. However, in BLW infants feed themselves all of their complementary food, in the form of graspable pieces of food, from the very beginning of the complementary feeding period⁵:

a clear contrast to the graduated exposure to different food textures which is recommended in conventional feeding. The key features of the BLW approach are:^{5,10}

- the infant sits with the family at mealtimes
- the infant is offered the same (healthy) food as everyone else, at first in large pieces, then in smaller pieces as they become a more proficient eater
- the infant feeds themselves, first using their hands and later using cutlery
- the infant chooses how much food they consume and how quickly they eat
- milk feeding (ideally breast milk, but formula may be used) continues on demand, unconnected with mealtimes, for as long as the infant wishes

The first foods recommended in BLW are those which can be easily picked up. Often this means that food will be cut into 'stick' shapes (such as sticks of cooked vegetables, strips of meat, sticks of cheese, or 'fingers' of toast) or that items with natural 'handles', such as broccoli or cauliflower florets, will be offered⁵.

Proposed advantages of baby-led weaning

Because babies who follow BLW are allowed to choose what, how much and how fast they eat, it has been suggested that as they grow, they will maintain better energy self-regulation abilities than conventionally fed infants, whose food intake during spoon-feeding is largely controlled by the parent^{5,9,27}. This has important implications for obesity prevention, as there is increasing evidence that better energy self-regulation is associated with a lower risk of obesity²⁸. It has also been suggested that BLW may promote acceptance of a wider range of foods as a result of earlier exposure to a greater range of tastes and textures than in conventional infant feeding methods, and that it may promote more highly developed motor skills in infants⁵ because it is likely to provide more opportunities (both in frequency and duration) for infants to develop their fine and gross motor skills earlier⁹.

The BLW approach may align with the principles of responsive eating to a greater degree than conventional complementary feeding²⁹. In one cross-sectional study, mothers following a baby-led feeding style reported significantly lower levels of restriction, pressure to eat, monitoring and concern over child weight than mothers following a standard infant feeding style³⁰. These characteristics could potentially have a positive impact upon later child weight

and eating style³⁰. In comparison, it has been recognised that adult feeding of puréed foods to infants can be coercive and may lead to food refusal, as well as delays in the development of self-feeding and social skills³¹⁻³².

On a further positive note, following a baby-led approach has been identified as a strong predictor of the introduction of complementary foods at the recommended age³³. However, it is also important to note that mothers who follow BLW are known to be different to other mothers: they are more likely to breastfeed, have more years of education, and are less likely to return to work before 12 months post-partum than other mothers⁷. This means it is difficult to determine whether BLW leads to the positive effects reported, or whether these are a result of maternal characteristics that made BLW attractive as a feeding method in the first place.

Finally, the later age at which complementary feeding is now recommended may coincide with the developmental readiness required for BLW to be successful^{5,9,26}. Previously, when the recommended age for beginning complementary foods was 4-6 months, purées and spoon-feeding may have been necessary because most 4 month old infants cannot sit unsupported, or chew food^{5-6,9-10}. However, by 6 months, most children are able to sit unsupported, and to reach out for and eat finger foods^{10,26}. Several authors have expressed surprise that little attention was paid to the manner in which the first solids are offered when the age of introducing complementary food was increased, given the physical differences between infants of 4 and 6 months of age^{6,9,29}. While some agencies, such as the United Kingdom (UK) Department of Health, and Health Canada, suggest that finger foods can be offered as part of the diet from the beginning of the complementary feeding period at 6 months of age, they do not recommend a baby-led approach in which the entire diet is self-fed²⁴⁻²⁵. Overall, recommendations in most countries have remained largely unchanged over the past 15 years, despite the increase in the age of introduction of complementary foods^{6,9}.

Possible disadvantages of baby-led weaning

Three important potential concerns with BLW are repeatedly raised in the literature: namely, whether BLW is associated with an increased risk of a) iron deficiency, b) food-

related choking and c) growth faltering in infants^{9,11,29}. High iron foods are necessary at 6 months of age to maintain iron status²¹; however, many common first foods, such as fruit and vegetables, are low in iron⁹. Infants following conventional feeding methods will commonly be fed fortified baby cereals as an important source of iron³⁴, but these are unlikely to be given in BLW due to their relatively liquid consistency⁹. A PhD candidate is responsible for investigating the risk of iron deficiency among infants in the BLISS study. Concerns about food-related choking and growth faltering centre around whether 6-month old infants can safely manage whole foods in the mouth, and whether they have the motor skills and motivation required to feed themselves the amount of food required to support optimal growth¹¹. These topics are the major focuses of this thesis and are discussed in detail in Sections 2.3 and 2.4 of this literature review.

There is no agreed definition of 'BLW'. While the original book by Rapley and Murkett suggests that purées do not need to be used at all during complementary feeding⁵, in the literature on BLW some authors have included limited use of spoon-feeding and purées (<10%)^{7,29}. Moreover, many studies have simply recruited participants who identified themselves as following BLW with their infants without using an objective definition^{11,33,35-36}. As pointed out by Cameron et al, such self-selection results in much ambiguity⁶. Furthermore, the examination of popular BLW websites supports the suggestion that the exact methods used by parents who believe themselves to be following BLW are variable⁶.

Baby-led weaning in its entirety may not be suitable for some infants, such as those with delayed development, muscle weakness or physical disabilities^{5,10,26,29}. Rapley and Murkett suggest that the parents of babies who were born prematurely or who have medical or physical problems seek advice from their paediatrician, dietitian and/or speech language therapist before using BLW as the only method for introducing complementary foods⁵.

Perhaps the largest disadvantage of the BLW approach at present is the lack of high-quality research about its safety and efficacy. To date, there are no published results of randomised controlled trials whereby infants and their families have been randomised to follow a baby-led approach and the outcomes compared to those of other infants and families following conventional feeding practices⁹. The research which does exist, while promising, must be

interpreted with caution due to a number of limitations, including cross-sectional study designs^{7,11,13-14,30,35-37}, small sample sizes^{8,11,14,36,38}, varying methods of participant recruitment (including a tendency toward self-selected samples)^{7-8,11,13,14,30,35-38}, a lack of control groups^{11,14,35} and differing definitions of BLW^{7-8,11,13-14,30,35-38}. Without a randomised controlled trial which accounts for both known and unknown confounders in the study population, it is impossible to establish any causal relationships between baby-led approaches to infant feeding and health outcomes. Such a trial is therefore urgently required before it is known whether BLW can be recommended as a population approach to infant feeding.

2.3 Choking

2.3.1 Background

Choking is a potentially fatal event which occurs when respiration is interrupted because a foreign object has been inhaled and has partially or completely blocked the internal airways, which include the pharynx, hypopharynx and trachea³⁹⁻⁴⁰. This process is often referred to as 'foreign body inhalation'. Foreign bodies may be organic or inorganic; food and food-related items (such as the bones of meat and fish) are considered to be 'organic', while non-food items (such as coins, toys, magnets) are described as 'inorganic'⁴¹. This thesis focuses on choking caused by the inhalation of organic foreign bodies in the form of food.

Although it is possible for people to choke at any age, infants and children aged 3 years or younger are at greatest risk^{1,39,41}. In New Zealand between 2002 and 2009, 16 children and young people aged 0-24 years died from foreign object inhalation⁴². Twelve of the 16 deaths occurred in children aged 3 years or younger, and foodstuffs (grapes (n=1), apple (n=1), meat/sausages (n=5) and peanuts (n=2)) were implicated in 9 of the 16 deaths⁴². However, mortality represents only a small proportion of the overall health burden associated with foreign body inhalation: European data suggests that for every child who dies, another 10 are hospitalised⁴³. Non-fatal choking incidents can have severe acute or chronic health consequences, such as aspiration pneumonia, oesophageal perforation and anoxic brain

damage^{41, 44}. It is also important to note that choking episodes which are resolved without medical attention are not reported and therefore are not included in health statistics^{40,42}.

For a number of reasons, infants and young children are at greater risk of choking than other age groups. First, their air and food passages are small in diameter (for example, the diameter of a child's trachea is similar to that of their little finger^{1,42}), which means that their airways are more vulnerable to obstruction by small foreign bodies³⁹. Incomplete dentition and an underdeveloped ability to chew and swallow food are also factors which have an impact^{39,45}. Dentition initially develops with the eruption of the incisors, with several months elapsing before molars follow⁴⁶. Thus for a significant period of time children are able to bite off portions of food without being able to grind them thoroughly before swallowing⁴⁷. Mature mastication abilities and the neural coordination of swallowing take time to develop, remaining relatively incomplete throughout early childhood⁴⁸⁻⁴⁹.

Furthermore, if the airway does become partially or completely blocked, a child's cough may be less effective in dislodging the foreign object because the force of air generated is less than it would be in an adult³⁹⁻⁴⁰. In addition to these physiological factors, young children have a natural tendency to put both nutritive and non-nutritive items in their mouths when exploring their environments^{42,50}. Unfortunately, they do not have a corresponding ability to assess the safety of each item⁴⁷ and they also have a tendency to be easily distracted when eating^{39,45} which further adds to the risk of choking.

Children with developmental delay, swallowing or neuromuscular disorders, traumatic brain injuries and other primary and secondary medical conditions are at greater risk of choking than other children³⁹. Regardless of the child's age, parents and caregivers of these children need to pay particular attention to choking prevention³⁹.

2.3.2 Foods involved in choking events in infants

Data describing the foods actually choked on by infants and very young children are limited, with most existing work defining 'children' as those aged between 0 and 14 years. Chapin et al investigated the epidemiology of non-fatal choking incidents among 0 to 14 year olds who had required treatment in hospital emergency departments in the United States of America and found that of all known food types, those most commonly responsible for choking

events were hard candy (15.5% of events), other candy (12.8%), meat other than hot dogs (12.2%), and bone (12.0%)⁵¹. However, the mean ages at which children choked on each of these items were all >3 years (range 4.0 years for hard candy to 7.6 years for bone). When data were limited to children aged <1 year, milk (including breast milk, formula and other milks) was responsible for 36.3% of all choking episodes⁵¹. Altkorn et al⁴⁵ retrospectively investigated the foods involved in fatal and non-fatal food injuries in 0 to 14 year old children and found that peanuts caused the highest frequency of injury, while hot dogs were most often associated with fatalities. Lists of the 'Top Ten' foods most frequently responsible for fatal and non-fatal food injuries were produced, with peanuts, hot dogs, unspecified 'meat', popcorn, carrots, apples, and candy each appearing in both lists. However, food injuries were not limited to choking in Altkorn's work; aspiration, ingestion and insertion were also included⁴⁵. Unspecified nuts were the most commonly documented food in a 2012 meta-analysis of studies of foreign bodies in the airways of children⁴¹. However, the age range of the children in the studies included in the meta-analysis is unclear.

An alternative approach to naming specific foods that are thought to pose a choking risk is to describe the hazardous characteristics of such foods. For example, a food which is a cylindrical shape, a similar size to a child's airway, and which has a compressible nature (such as a hotdog) has several characteristics which predispose it to becoming wedged in an infant or child's airway^{39,51}. The NZ MOH has produced detailed information about the characteristics of foods that are thought to pose a choking risk for children aged less than five years (Appendix A)¹. This information is summarised in **Table 2.2**.

Table 2.2 Common characteristics and examples of foods which are thought to pose a choking risk to children aged <5 years¹

Food Characteristic	Reason for associated choking risk	Food examples	Relevant advice
Small, hard item	Difficult for children to bite through and break down enough to swallow safely.	Nuts	Do not give whole nuts to children <5 years
	Pieces can become stuck in airways.	Raw apple	Cook until soft, or grate finely
Small round or oval item	Items of these shapes can lodge in children's airways.	Grapes	Chop into halves, quarters or smaller pieces
	Children do not have the ability to chew hard, small round items adequately.	Lollies	Do not give to children <3 years
Foods with skins	Difficult to chew and can completely seal children's airways.	Chicken skin, sausages	Remove skins before serving
Compressible foods	Can conform to the shape of the airway and become tightly wedged	Sausages, saveloys, hot dogs	Chop finely before serving
Thick pastes	Can conform to the shape of the airway and stick to its sides	Peanut butter	Use sparingly and spread evenly onto bread
Fibrous or stringy foods	Difficult to break into smaller pieces	Celery	Peel off strong fibres; slice thinly

¹This table is an abridged version of the table produced by the New Zealand Ministry of Health¹ (for the full table see Appendix A).

2.3.3 Prevention of food-related choking in infants

Infants and young children are completely dependent on parents and caregivers to provide safe food⁴⁷. Foods which are thought to pose a choking risk should not be offered to infants unless they can be altered in a way which reduces the risk⁴⁰. Parents and caregivers also need to promote safe, well-supervised feeding environments; eating should take place while infants and young children are seated (ideally in a highchair or similar seat) in a calm environment where they are encouraged to focus only on the activity of eating. Distractions such as walking, running, talking, lying down, laughing and crying while eating increase the risk of food-related choking^{1,39-40, 47}.

While at least one author has implied that choking can be prevented using public health strategies⁵², both the NZ MOH and the American Academy of Pediatrics (AAP) have stated that some choking events may still occur even when all preventive measures are in place^{1,39}. It is therefore of paramount importance that parents and caregivers supervise all eating occasions closely and understand choking first aid and cardiopulmonary resuscitation^{1,39-40} so that they can respond to choking events in a timely and appropriate manner.

2.3.4 Baby-led weaning and choking

A common concern with baby-led approaches to infant feeding is the possibility that they may be associated with an increased risk of food-related choking in infants^{6,9-10,14,29}. The safe management of pieces of whole food in the mouth is a complex process involving the co-ordination of chewing, swallowing and breathing⁵³ that may be difficult for 6-month old infants who are just beginning to experiment with food⁶. To date, there is very little published research in this area, and the research which does exist has clear limitations.

Research

In 2012, Cameron et al interviewed 31 New Zealand-based health professionals and found that most were reluctant to recommend BLW due to concerns that 6-month-old infants would not be developmentally ready to chew whole pieces of food¹¹. Some also expressed concern that infants could potentially be left alone in their highchairs with food during BLW, whereas spoon-feeding requires the parent to be within arm's reach of the infant. A group of mothers (n=20) who self-identified as having followed BLW with their infants were also

interviewed¹¹. Interestingly, they did not report feeling concerned about the risk of food-related choking during BLW; however, 30% (n=6) could recall at least one occasion on which their infant had choked. Further questioning revealed that raw apple (which should not be offered to infants¹) was the food most commonly responsible for these episodes, leading Cameron et al to later suggest that parents following BLW in the community lacked knowledge about which finger foods were safe to offer⁵². However, the study was very small and only included parents who volunteered to be interviewed about following BLW so is not likely to be representative of all families who have tried BLW.

In another study by Cameron et al, a small internet-based survey was used to compare the behaviours of 199 parents from urban areas of New Zealand who were following either traditional feeding practices or varying degrees of BLW¹³. Mothers in this study who did not want to try BLW most commonly cited fear of choking as the reason for avoiding the approach. No differences in the rates of choking between study groups were found (31% of traditionally-fed infants had choked, compared with 31-40% of infants following BLW to varying degrees)¹³. However, the survey was not powered to identify group differences in choking rates.

As part of the preparatory work for the BLISS randomised controlled trial, a small pilot study was conducted³⁸. Infants who followed the BLISS approach to complementary feeding (n=14) were less likely to be offered foods which were thought to pose a choking risk than infants following BLW in the community (n=9) (3.24 vs 0.17 serves per day, $p = 0.027$), although the rates of actual choking events between the groups did not differ. However, only 3 choking events were reported across both groups over the 12-week study period³⁸.

In one other study, also from the BLISS research group, the weighed diet records of 51 six-to-eight month old infants were analysed to see whether those following BLW (n=25) were more likely to be offered foods thought to pose a choking risk than those following traditional spoon feeding (TSF) practices (n=26)³⁷. Seventy-eight percent of infants following BLW were offered foods which were thought to pose a choking risk, compared to 58% of infants in the TSF group. Although no statistically significant difference was observed between groups (OR 2.57, 95% CI 0.63 to 10.44), the authors highlighted the broad width of

the confidence interval. Because it included values which were consistent with an important potential increase in the odds of infants following BLW being offered foods thought to pose a choking risk, it was not possible to exclude the possibility that BLW infants were more likely to be offered potentially hazardous foods than infants following TSF practices³⁷.

Views of the founders of baby-led weaning

In their book 'Baby-led Weaning', Rapley and Murkett suggest that choking is no more likely among infants following BLW than it is among infants following conventional feeding practices⁵. Rather, they suggest it may actually be less likely, provided that three conditions are met. First, infants must sit upright (supported if necessary) when eating; second, they must be in control of what goes in their mouths, and third, they must not be given foods which are obvious choking hazards. When these conditions are met, infants are provided with the opportunity to learn to safely manage whole food in the mouth from the very beginning of the complementary feeding period. By comparison, at the beginning of conventional complementary feeding, the infant learns only to suck puréed food from the spoon to the back of the mouth, where it is swallowed without any chewing⁵. This does not teach the infant about how to manage foods which need to be chewed before they are swallowed, and as a result, Rapley suggests that spoon-fed infants may have more problems with choking when they do start to handle food, than BLW infants who have been allowed to experiment from the beginning of the complementary period⁵.

The BLW book states that choking events where the airway is completely blocked, so that the child is unable to cough to clear the blockage, are very rare and would require someone else to dislodge the lump using 'standard first aid procedures'⁵. Unfortunately, such procedures are not described in the book, which includes only one short paragraph outlining foods which constitute choking hazards (Appendix B). Overall, it is concerning that those who read the book could be left with the impression that BLW does not increase (and potentially decreases) the risk of food-related choking in infants, when in fact there is currently a lack of high quality research to confirm these hypotheses.

2.3.5 Baby-led weaning and gagging

Rapley and Murkett emphasise that gagging is often mistaken for choking, although the two are actually separate events^{5,10}. In the BLW book, gagging is described as a retching movement which pushes food away from the airway if it is too large to be swallowed⁵. The authors explain that this movement is triggered further forward on the tongue of a 6-month old infant than it is on the tongue of an adult, so infants gag more easily than adults, including when food is far from the airway. Scientific literature supports this view: the area of stimulation for gagging (which is described as an involuntary reflex which stops foreign objects entering the airway⁵⁴⁻⁵⁵) is known to decrease over time¹⁴. The gag reflex develops in an unborn child in the third trimester of pregnancy and is initially stimulated when the posterior two thirds of the tongue or the pharyngeal wall are touched¹⁴. However, after birth and as the infant grows, the area of stimulation gradually decreases to about a quarter of the posterior tongue, and the reflex becomes less intense¹⁴.

Rapley describes gagging as a “safety feature” which is common in the early stages of BLW, as infants learn how much food to put in the mouth and how far back to push it^{5,10,29}. It is expected that once they have gagged a few times, infants will have learnt what triggers the reflex, and will be able to avoid it, so gagging will quickly become less frequent⁵. In comparison, infants who have not been allowed to explore food from the beginning of the complementary feeding period may miss out on this learning opportunity, because the gag reflex will have moved further back on the tongue by the time they begin to handle food⁵.

To date, the only research to include measures of gagging among infants during the complementary feeding period is the small BLISS pilot study³⁸. No differences were found in the proportion of families following BLISS and BLW who reported a gagging incident when infants were 6, 7 and 8 months old³⁸.

2.3.6 Differentiating between choking and gagging events

Some parents are not able to differentiate between choking and gagging in their infants^{13,38}, which may result in an overestimation of true choking rates. This may happen even when parents are provided with detailed information about the differences between choking and gagging¹³. Mothers in several studies have reported that the differences between choking

and gagging became more obvious over time, as infants become more skilled feeders^{11,13,38}.

Table 2.3 outlines the characteristics of each event.

Table 2.3 Differences between food-related choking and gagging in infants

	Gagging	Choking
What is it?	A protective reflex to stop foreign items (including food) entering the airways ⁵⁴⁻⁵⁵	Interruption of respiration because a foreign item is in the airway ³⁹⁻⁴⁰
Is the child's airway obstructed?	No	Yes, either partially or fully ³⁹⁻⁴⁰
What symptoms are observed?	The foreign item is ejected by contraction of the oropharyngeal muscles ⁵⁵ ; food may appear at the front of the mouth ⁵ . There may be an accompanying retching sound and/or vomiting ⁵⁵ . The infant may then carry on as if nothing has happened ⁵ .	Symptoms will vary between patients and also depend on whether the obstruction is partial or total. Partial obstruction: ⁵⁶ <ul style="list-style-type: none">- breathing laboured, gasping or noisy- some air escaping from mouth- coughing or making a 'crowing' noise- anxiety/agitation- pale or bluish skin colour Total obstruction ⁵⁶ : <ul style="list-style-type: none">- unable to effectively cough, breathe or verbalise (no air movement)- obvious effort to breathe with in-drawing of the spaces between the ribs and above the collarbones- face greyish in colour and lips blue due to lack of oxygen- clutching at the throat with both hands
How is it resolved?	By the ejection of the foreign item from the area near the airway	A partial obstruction may or may not be resolved by the infant coughing (see below). An infant with a total obstruction will require assistance.

What actions should the parent/caregiver take during the event?	Remain calm; talk to and reassure the infant ⁵ .	<p>Partial obstruction:⁵⁶reassure the infant and encourage them to cough to expel the foreign body If the obstruction is not relieved, call 111 for ambulance (do not give back blows if the infant is able to cough or breathe)</p> <p>Total obstruction:⁵⁶</p> <ol style="list-style-type: none"> 1. Call 111 (take baby with you to do this) <p>If infant is conscious:</p> <ul style="list-style-type: none"> - place them face-down on your lap, support their head and give up to five firm back blows, using the heel of one hand - if unsuccessful, place the infant face upwards across your lap and give up to five chest thrusts just below the nipple line. Check after each thrust to see if the object has been dislodged - if the obstruction has not been relieved, alternate between back blows and chest thrusts until the ambulance arrives <p>If infant is unconscious:</p> <ul style="list-style-type: none"> - quickly check the mouth and use fingers to clear any visible solid obstruction - begin CPR and continue until the ambulance arrives⁵⁶
What are the possible side effects?	The infant learns to keep food away from the airway until it is ready to be swallowed. ⁵	A range of outcomes are possible, from no lasting side-effects to serious acute or chronic consequences such as aspiration, oesophageal puncture, hypoxic brain injury, and death. ⁴¹

2.3.7 Summary and recommendations for this project

Infants and young children are already at greater risk of choking, and its potentially severe consequences, than older children and adults^{39-40,45}. The possibility that baby-led approaches to infant feeding may further increase the risk of food-related choking in infants therefore requires thorough investigation before such approaches could be recommended at a population level.

Pilot work suggests that a modified version of BLW, named the 'BLISS' approach, can address some of the concerns around choking in baby-led approaches to infant feeding³⁸. However, this needs to be confirmed by a larger study, which is one of the objectives of the BLISS randomised controlled trial. The results of the BLISS pilot study, and of Section 2.2 of this literature review, suggest that the BLISS intervention should follow the principles of BLW as closely as possible while also including some modifications which address concerns about choking risk. In particular, the intervention should include:

- detailed advice about how to identify, prepare and provide foods which are not thought to pose a choking risk to, and can be safely self-fed by, six month old infants
- instructions about foods which are thought to pose a choking risk and which should not be offered to infants
- instructions about safe parental feeding practices and close supervision of all infant eating occasions.

Methods to measure rates of choking and gagging should address the difficulties which parents experience when trying to differentiate between food-related choking and gagging in their infants. All families in the study should therefore receive:

- education on the differences between the two events, so that each can be correctly recognised
- information about how to respond to each event, including instructions about First Aid for food-related choking events.

2.4 Growth faltering

2.4.1 Background

In the literature, a range of terms including 'weight faltering', 'failure to thrive', 'growth faltering', 'malnutrition', and 'underweight' are used to describe various manifestations of poor growth in infancy and childhood. Broadly speaking, the meaning of these terms can be described as 'inadequate physical growth diagnosed by observation of growth over time using a standard growth chart'⁵⁷. In recent years, there has been a trend away from the term 'failure to thrive' due to its broad, non-specific nature⁵⁸ and because of negative connotations arising from its early definitions, which included emotional and behavioural symptoms and strong links with maternal deprivation and psychosocial adversity⁵⁹⁻⁶⁰. The terms 'weight faltering' and 'underweight' (which is defined by the WHO as a weight-for-age z-score of below -2⁶¹, but which has also been defined differently by other authors²⁷) may imply that other growth indices have not been considered or are not of concern, while the term 'malnutrition' has sometimes been used to describe conditions of over- as well as under-nutrition⁶². Consequently, the term 'growth faltering' will be used throughout this thesis.

The prevalence of growth faltering in a particular population is dependent on the criteria being used to define the condition and on the demographics of the population being studied⁶³⁻⁶⁴. By strict statistical definition, in a normally distributed healthy population, 3% of the paediatric population will deviate from normal stature or weight for age and gender⁶⁶. Data from the USA have suggested that growth faltering is seen in 5 to 10 percent of children in primary care settings and in 3 to 5 percent of children in hospital settings when different measures are used to define growth faltering¹⁰⁰. However, more recent estimates from the UK suggest that when growth faltering is defined by the downwards crossing of more than 2 centile spaces on the UK-WHO CGS, only 0.5% of children will display growth faltering after the first four months of age⁶⁷. Different results may be observed in low and middle income countries: in 2010, Victora et al used data from children aged 0 to 59 months in 54 such nations to describe worldwide growth faltering patterns using the WHO-CGS⁶⁸. Rapid growth faltering was observed until 24 months of age, leading

the authors to highlight the first two years of life as a 'window of opportunity' for the promotion of appropriate infant feeding practices to prevent growth faltering⁶⁸.

Growth faltering has historically been categorised as being of either organic (medical) or non-organic (social, environmental or other) causation⁶⁹. Medical causes are found in only a small minority ($\leq 10\%$) of cases, and virtually all children with underlying medical conditions are identified by a careful history and a physical exam^{66,70}. In such cases, treatment is determined by the characteristics of the newly diagnosed condition⁶⁶. In the remaining $\geq 90\%$ of cases, growth faltering is increasingly being recognised as a physical sign that a child's nutrition is inadequate for optimal growth and development⁷¹⁻⁷³. Growth faltering can be further categorised as undernutrition due to one of three factors: inadequate caloric intake, inadequate caloric absorption, or excessive caloric expenditure⁷². Inadequate caloric intake is the most common aetiology and has a number of possible causes, such as breastfeeding difficulties, insufficient breast milk or formula consumption, and difficulty transitioning to solid foods^{69,66}. Psychosocial and environmental factors, such as poverty, lack of parental nutrition knowledge, or parental ill health, may also contribute to growth faltering; for this reason growth faltering is often considered as being of multifactorial origin⁷²⁻⁷³. Nutritional management of growth faltering is essential to promote catch-up growth and to reduce the short and long term impacts of growth faltering⁷⁴⁻⁷⁵. The first line of treatment should be nutrition counselling; however, oral nutritional supplementation may be required if improvements are not achieved with counselling alone⁷⁶. Nutritional management of growth faltering should focus on providing adequate energy and protein intakes in ways which are realistic and achievable for the child and family⁷⁴. Regular monitoring is required so that the child's nutritional requirements can be adjusted as necessary⁷⁴.

Numerous studies have investigated the neurodevelopmental and growth sequences of children with growth faltering⁷⁷⁻⁷⁸. Most demonstrate adverse outcomes, although in some cases questions of clinical significance have been raised⁷⁸. In a 2004 meta-analysis, growth faltering was associated with adverse intellectual outcomes which were large enough to be considered important at a population level (mean difference of -4.2 Intelligence Quotient (IQ) points)⁷⁷. A 2005 systematic review found that children with growth faltering had IQ

scores which were 3 points lower than expected and were shorter and lighter at follow-up (measured at 3 years of age or older). However, the authors of the review suggested that the clinical significance of the differences was questionable for both clinical and methodological reasons⁷⁸. Individual studies in which infants or toddlers who had growth faltering were followed for up to 8 years have reported measurable deficits in IQ, learning difficulties, and behavioural difficulties⁷⁹⁻⁸⁰. Timing was a crucial factor in at least one of these studies⁸⁰; Emond et al found that while growth faltering between birth and 8 weeks of age was associated with persisting deficits in IQ at 8 years, the extent of weight gain from 8 weeks to 9 months was not related to IQ at 8 years.

Although it is widely believed that individuals who experienced growth faltering as infants will be small throughout their lives, the long-term growth of such individuals is widely discrepant⁸¹. In 2014 Kim reported on a group of infants who overcompensated their goal weights after treatment for growth faltering, leading to the suggestion that aggressive treatment of growth faltering may in fact lead to obesity⁸². However, by the authors' own admission, this was a very small observational study including only 6 infants who were all of African-American ethnicity⁸². Furthermore, even those who have disputed the clinical significance of differences between growth faltering and non-growth faltering children have stated that there is still benefit in identifying children who are growing poorly, and that the challenge for healthcare professionals is how to identify those children among the slowest growing who would benefit from investigation or intervention, without generating unnecessary anxiety in those that do not⁷⁸.

2.4.2. Identifying growth faltering

Three components are required to assess a child's growth and determine the presence or absence of growth faltering⁶³:

- a growth standard or reference
- anthropometric measurements
- a threshold or cut-off point for differentiating 'normal growth' from 'growth faltering'

Growth standards and references

One of the most important steps in assessing a child's growth is to plot anthropometric measurements on a growth chart, which is based on a growth reference or a growth standard appropriate for children of that age and sex⁸³⁻⁸⁴. There are important distinctions between 'growth standards' and 'growth references'⁸⁵⁻⁸⁶.

A number of growth references are available worldwide; most are based on cross-sectional data from localised populations where rates of breastfeeding and other health indicators vary⁸⁶. For example, in this country, the New Zealand Growth Charts (NZGC) (1991) were a commonly used reference between 1991 and 2008: they were based on a 1989 study of 12,311 children aged 1 month to 5 years from 10 localities across New Zealand⁸⁷. The sample included both breastfed and formula fed infants⁸⁷. It is now widely recognised that cross-sectional growth references such as the NZGC only describe *how* children in a certain population were growing at the time that the data was collected⁸⁵⁻⁸⁶. By contrast, growth standards describe how healthy children *should* grow, regardless of locality, if they are living under conditions which favour the attainment of their full genetic growth potential⁸⁵⁻⁸⁶.

In 2006, the WHO published new Child Growth Standards (WHO-CGS), including growth charts for infants and children aged 0-5 years⁸⁵. Prior to this, the WHO had adopted growth charts which were initially created in 1977 by the National Centre for Health Statistics (NCHS) for use in the United States of America (USA)⁸⁸. In 2000, after it had become apparent that the NCHS reference had a number of limitations, the charts were revised into the Centers for Disease Control (CDC) growth charts⁸⁹. Briefly, the limitations of the NCHS reference included that data came only from one area in the USA; the participating children were all of European ancestry and the majority were fed artificial milks; and although repeated measurements were taken, the intervals between them were long – up to 3 months in the first year of life⁸⁹, when infants are growing and changing rapidly⁷¹. There were also statistical shortcomings, inherent to the methods available at the time, in the generation of the NCHS growth curves. While the revision was able to address some of the limitations of the NCHS reference by using improved statistical procedures and incorporating new national (albeit cross-sectional) survey data⁸⁹, the CDC charts still

constitute a reference rather than a standard and the USA have subsequently adopted the WHO-CGS for monitoring the growth of 0-2 year old children⁸⁸.

The 2006 WHO-CGS were created using data from the Multicenter Growth Reference Study (MGRS), which was designed to produce a standard rather than a reference⁸⁵. Between 1997 and 2003, longitudinal growth measurements were collected from 8440 healthy breastfed children of smokefree mothers living in favourable conditions in six diverse countries - Brazil, Ghana, India, Norway, Oman, and the United States of America. The linear growth of children from all of the six sites was found to be very similar, indicating that regardless of location and ethnicity, healthy children will grow in similar ways, at similar rates⁸⁵. In 2006, the WHO recommended that the new charts be applied to children everywhere because they represent the best available description of physiological growth⁸⁵. By April 2011, 125 countries who together represented 75% of the world's population aged <5 years, had adopted the WHO-CGS⁹⁰⁻⁹¹. Thirty countries had chosen not to adopt the standards, mainly because they preferred to use existing local references, and the standards were still under consideration in a further 25 countries⁹⁰. Generally, countries who did adopt the standards did not do so lightly: the standards underwent greater scrutiny than any previous growth assessment tool⁹⁰, which is justifiable when their potential effects on national healthcare policies and on clinical care and growth monitoring processes are considered^{86,92}. There has been some debate in the literature about how well the growth of children in various countries compares to the standards; while some have suggested that the use of local references to monitor child growth might be more appropriate in some populations⁹³⁻⁹⁴, others have disputed such suggestions^{86,95-96}.

In the UK, the WHO-CGS were deemed appropriate for use in children aged 2 weeks to 4 years old⁹⁷, but not for infants aged 0-2 weeks because data from two UK cohorts suggested that the WHO birthweight standard was not representative of UK birthweights⁹². Clinicians in the UK currently use the 'UK 1990' reference for assessing birth weight, and the WHO-CGS standard for children aged 2 weeks to 4 years. The growth charts used in the UK are thus referred to as the UK-WHO charts⁹⁷. New Zealand (NZ) chose to adopt these and in this country they are subsequently referred to as the NZ-WHO charts⁹⁸ (Appendix C). The NZ-WHO charts have been considered a more appropriate measure than the previous NZGC

reference because the NZ-WHO charts are based on breastfed babies, and because the NZGS do not reflect the current New Zealand population because Māori and Pacific ethnicities were under-represented in the 1989 survey¹. Although New Zealand has adopted the UK-WHO charts, the NZ MOH has pointed out that individual circumstances should always be considered when assessing the growth and development of infants and children¹. They also recognise that breastfed Pacific children born in New Zealand to smokefree mothers are bigger and grow at a faster rate than other New Zealand children⁹⁹. While the WHO have stated that their charts are appropriate for all children regardless of ethnicity⁸⁵, the NZ MOH state that extra care is required when using them to monitor the growth of Pacific children¹.

Anthropometric measurements

In 1985 a consensus was reached that anthropometric measurements were required as the basis for diagnosing growth faltering, rather than a range of other indicators previously used in the literature (such as the presence or absence of somatic illness and of emotional or behavioural symptoms)⁵⁹. For monitoring and assessment of growth, a series of anthropometric measurements over time are necessary because one-off measurements do not reflect growth patterns¹⁰². Advantages of anthropometric measurements include that they are inexpensive, fast, non-invasive and can be performed using portable equipment¹⁰⁰⁻¹⁰¹. They also provide indications of both short and long term nutrition status¹⁰⁰. However, it is well recognised that the accuracy and reliability of anthropometric measurements can be affected by systematic and/or random measurement errors¹⁰⁰⁻¹⁰¹, and thus for research purposes it is fundamental that such errors are minimized by:

- the use of standardised, validated measurement techniques
- the use of high-quality equipment which is regularly calibrated and accurate
- the employment of trained measurers with consistent and accurate techniques.

It is notable that even with these steps in place, factors such as the setting in which measurements are taken, the behaviour and cooperation of the child being measured, and

the mood and fitness of the anthropometric measurer, may impact on measurement accuracy¹⁰³.

Which anthropometric measurements should be used?

The most widely used measurements of growth are those of body weight and stature (height or length), although other measures such as circumferences and skinfolds may also be used¹⁰⁴⁻¹⁰⁵. For example, in the longitudinal component of the MGRS, weight, recumbent length and head circumference were measured from birth to 24 months of age, and arm circumference, triceps and subscapular skinfolds were measured between 3 and 24 months of age⁸⁵.

- **Weight** is the most common measurement: it is generally a practical, simple and accurate choice¹⁰⁵, although it can be affected by stomach and bladder volume¹⁰³. Children should ideally be weighed nude^{83,100}, or in light clothing such as a dry nappy⁹.
- **Recumbent length** is also a common measurement and is preferred to standing height in 0-2 year olds⁶⁹. However, the inaccuracy of length measurements is well documented and is a known risk for misdiagnosing children with growth faltering^{69,106}. Standardized procedures must be followed in order to minimize measurement errors⁶⁹.
- **Head circumference** reflects brain growth in the early years of life⁶⁹; the expected average increase in the first year of life is 10cm¹⁰⁰. Faltering growth in this area may suggest problems with brain growth or severe extended malnutrition¹⁰⁰.
- **Skinfolds and arm circumference** provide information about children's body composition and subcutaneous fat⁶⁹; this can be useful as such information cannot be attained from weight and length measures alone¹⁰⁰. However, these measurements are prone to a greater degree of error than other growth indicators

and may be difficult to interpret, even when they are collected by well-trained anthropometrists using standardized equipment¹⁰².

How often should anthropometric measurements be collected?

While the tempo of growth in early life is rapid¹⁰⁷, to the degree where some authors have listed expected weight gain in the first 18 months of life in grams per day⁷³, growth actually occurs in 'spurts', with rapid growth followed by slower growth¹⁰⁰. Furthermore, the fuelling of rapid growth requires intensive feeding; any illness or upset which interrupts feeding is likely to produce at least temporary growth faltering¹⁰⁷, although this usually resolves very quickly (within 2-3 weeks)¹⁰⁸. Therefore, researchers must carefully consider the time period between measurements. Measurement error is greater over shorter periods of time¹⁰⁹, and natural variability may be greater than potential weight gain if weights are recorded at intervals which are too close together¹¹⁰. It is therefore important that measurements are not taken too frequently; however, in order for potential problems to be identified early⁸³, they also must not be taken too infrequently. Clinical recommendations from the UK suggest that even when there is concern, infants should be weighed no more often than a) monthly before 6 months of age, b) two monthly between 6-12 months of age, and c) every three months after that¹¹⁰. In New Zealand, it is recommended that infants are only weighed at routine Well Child checks¹⁰⁸. This equates to five weight measurements between 6 weeks and one year of age (at 6 weeks, 8-10 weeks, 3-4 months, 5-7 months and 9-12 months)¹¹¹. Unlike the UK, in New Zealand additional measurements are recommended if there is concern about an infant's weight gain, growth or general health, although it is also recognised that weights taken at close intervals can be misleading¹⁰⁸. Notably, infant weights have been taken more frequently in some research settings, such as in the longitudinal component of the MGRS⁸⁵, where monthly measurements were taken throughout the first year of life.

Thresholds/cut-off points

It is necessary to have thresholds or 'cut-off' points in order to differentiate children who are growing slowly, or not growing at all, from children who are growing normally^{58,107}. A range of criteria, mostly involving weight measures, have been used in the literature^{58,64}.

Common choices include low weight-for-age (i.e. weight below a certain percentile, or below a certain standard deviation from the mean) and downward crossing of weight over two or more main percentile lines on growth charts. By contrast, measures involving height (such as length-for-age and Body Mass Index (BMI)-for-age) have been used less frequently^{58,64}. The degree of concurrence between different criteria is poor, which was clearly demonstrated by Olsen et al in 2007 when seven different criteria (outlined in **Table 2.4** below) were applied to a cohort of 6090 Danish infants in two age groups (2-6 months and 6-11 months)⁶⁴.

Table 2.4 Seven possible ways of using anthropometric measures to define growth faltering¹

Measurement	Criterion
Weight-for-age	<75% of median weight for age (Gomez trigger)
Weight-for-length	<80% of median weight-for-length
BMI	<5 th centile for chronological age
Weight	<5 th centile for chronological age
Length	<5 th centile for chronological age
Weight deceleration	Deceleration crossing more than two of the following major centile lines: 5,10,25,50,75,90,95, from birth until current age
Conditional weight gain	Lowest 5%, adjusted for regression towards the mean from birth until weight within the given age group

¹As defined by Olsen⁶⁴

Twenty-seven percent of infants met one or more criteria in at least one of the two age groups, but no infants met all of the criteria, and most (623/942 from the younger and 804/1126 from the older age group) met only one criterion, thus demonstrating that different criteria will identify different populations as having growth faltering⁶⁴.

The limitations of some of the criteria used to diagnose growth faltering are well documented^{57,59,64,107}. For example, criteria based on weight being below a defined centile (such as the 3rd) will incorrectly identify constitutionally small children as growth faltering, while missing larger children who may have fallen through multiple centiles without passing

the cut-off^{59,107}. On average, lighter infants grow faster than heavier infants, who tend to 'regress towards the mean' over time¹⁰⁹. However, the percentile-crossing method may over-identify these larger children, while failing to recognise small infants with suboptimal growth because they are already on or below the lowest percentile lines and are therefore unable to downwards cross a further two⁶³. Because of these limitations, it has been suggested that single indicators alone should be used as a signal for further investigation⁶⁰, rather than as a way of identifying growth faltering. Current recommendations in the UK and New Zealand support this suggestion⁶⁷⁻¹⁰⁸. In the UK, an infant who falls through two centile spaces on the UK-WHO charts is generally considered to require closer assessment, although there are two exceptions: concern should be triggered if infants with a birthweight below the 9th centile fall through just one centile space, while infants above the 91st centile could cross three centiles before concern was raised⁶⁷. The NZ MOH suggest that infants and toddlers with a drop of two or more centiles on the NZ-WHO charts should be referred for further assessment, as should any infant with measurements which are consistently below the 0.4th percentile¹⁰⁸.

Measures of growth velocity

Age-dependent measures of growth velocity are able to identify subnormal rates of weight gain (rather than merely subnormal weight)¹⁰⁷ and therefore provide a useful measure of nutritional status in paediatric populations⁷¹. Growth velocities are commonly used in research settings. The first step is to choose a growth standard and evaluate anthropometric data against it by deriving a standard deviation or 'z-score' from the measurement and the child's chronological age, i.e. a weight-for-age or height-for-age z score¹¹². The z-score measures the deviation of the child's anthropometric measurement from the standard mean for a child of that age and gender¹¹². For example, a weight-for-age z-score of -0.5 indicates that a child's weight is 0.5 standard deviations lower than the standard or median for a child of that age and gender. In a research context, as the child grows and more measurements are collected, regression to the mean can be allowed for by using conditional weight gain, where a change in z-scores is adjusted for the baseline centile position⁶³. This allows a child's actual rate of weight gain to be compared with the expected rate of gain for children of that age and size¹⁰⁹.

2.4.3 Growth faltering and baby-led weaning

Research

As described earlier, the proposed advantages of baby-led approaches include improved energy self-regulation^{5,9,27-28}. It therefore seems incongruous that BLW would also be associated with an increased risk of growth faltering²⁹. However, there are as yet no data on energy self-regulation or risk of growth faltering from randomised controlled trials, so concern about a possible risk of growth faltering continues^{6,9,11}. In a New Zealand-based content analysis study, health professionals expressed concern that 6-month old infants following BLW would not consume enough calories to keep pace with growth, first because they may not possess the motor skills or motivation required to feed themselves enough food (particularly at the beginning of the complementary feeding period) and second because many of the first foods offered in BLW would be expected to be low in energy, such as fruit and vegetables¹¹. By contrast, only one parent in the same content analysis study was concerned about whether her infant would be able to eat enough, although many mothers reported spoon-feeding their BLW infants at times when they were at risk of inadequate intake (such as when they were unwell or very tired)¹¹. Recent work from the UK found that 15 mothers who were following BLW with their infant were unconcerned about potentially small intakes of solid foods at the beginning of the complementary feeding period⁸. Many of these mothers reported that although solid foods were offered from 6 months of age, infants did not actually ingest much until later in the complementary feeding period. Some of these mothers attributed their lack of concern to a belief that 'food before one is just for fun'⁸.

To date, only two cross-sectional studies have specifically reported the prevalence of 'underweight' among infants and children who have followed either baby-led or conventional feeding methods^{27,35}. In the first study, Townsend and Pitchford used the WHO criterion of weight-for-age z-score below -2 to define 'underweight'⁶¹ and found a greater incidence among children aged 20 to 78 months who had followed parent-reported BLW, compared to infants who were spoon-fed³⁵. However, limitations included the total number of underweight infants being very low (3 in the BLW group compared to 0 in the spoon-feeding group), participant recruitment methods differing between study groups, and

standardised measures for measuring height and weight only being employed in the spoon-feeding group³⁵. In the second study, Brown and Lee used a different definition of 'underweight' (infant weight <5th percentile for infant weight and gender according to the WHO-CGS), and found that 3.7% of infants following BLW (defined as using spoon-feeding and purées ≤10% of the time) met this criterion at 18 to 24 months of age, compared to 2.5% of spoon-fed infants²⁷. However, again the total number of infants classified as underweight was low (n=11), and the data were also limited by parent reporting of infant weights, which may be inaccurate¹¹³. As both studies were cross-sectional, neither included repeated anthropometric measurements or used measures of growth velocity to identify infants with growth faltering.

Views of the founders of baby-led weaning

Rapley has acknowledged that the actual intake of solid foods among BLW infants will probably be small at first, and she has also recognised that trusting infants to respond to their own appetite can be difficult for parents^{5,29}. However, she suggests that fears about inadequate intake are based on the unproven assumption that adults know more about how much food infants need than infants themselves, and she does not consider a limited food intake at the beginning of BLW to be problematic, provided that milk feeds continue to be given on demand²⁹. While it appears that some parents accept these suggestions when deciding to follow BLW with their infants⁸, it is important to note that to date, no studies have investigated whether the potentially small amount of food consumed by infants in the early days of baby-led approaches to complementary feeding is associated with an increased risk of growth faltering.

2.4.4 Summary and recommendations for this project

Although it seems feasible that infants following baby-led approaches could be prone to inadequate energy intakes, especially at the start of the complementary feeding period, to date only two very small cross-sectional studies with notable limitations have compared rates of 'underweight' in infants following baby-led approaches with those in infants following conventional complementary feeding practices^{27,35}. No longitudinal study has used repeated anthropometric measurements over time to identify growth faltering using a definition which includes a measure of growth velocity. Therefore, there is a clear need for a

randomised controlled trial to investigate whether baby-led approaches could predispose infants to growth faltering, before such approaches can safely be recommended at a population level. The findings of Section 2.3 of this literature review suggest that the BLISS intervention should follow the principles of BLW as closely as possible while also including some modifications which address concerns about potential growth faltering. In particular, the intervention should:

- include strategies for reducing the risk of inadequate energy intake among infants who are randomised to this study group
- encourage responsive feeding practices, such as allowing the infant to be in control of how much food is consumed at each meal
- include advice about 'easy to eat' options for times when infants' food intakes are reduced by illness or tiredness

The study will also need to include methods for identifying growth faltering among all participating infants, regardless of group allocation. These methods should address the following points:

- a clear definition of 'growth faltering' must be decided upon, and both the strengths and limitations of the chosen definition should be recognised when the study findings are presented
- growth faltering must be identified by repeated anthropometric measurements taken over time by well-trained anthropometrists who use standardised techniques and accurate equipment
- the amount of time between measurements must not be too short, or too long: monthly measurements have been used in other research settings
- a growth standard will be required; the WHO-CGS would be advisable because it is recognised as the best international definition of how healthy infants and children should grow.

It is also imperative that there is a plan for managing any cases of growth faltering which are identified during the study, regardless of whether or not they are a consequence of the intervention.

2.5 Summary

In summary, an increased risk of both food-related choking and growth faltering are two potential disadvantages of baby-led approaches to infant feeding. This literature review has evaluated current knowledge in both of these areas, and it is apparent that, to date, there are no published results of randomised controlled trials investigating whether the heightened concerns about food-related choking and growth faltering in baby-led approaches to infant feeding are justified. This thesis will address these gaps in the literature by determining whether a modified version of BLW alters the risk of food-related choking and growth faltering in infants aged 0-12 months.

3. Methods

3.1 Study design

3.1.1 BLISS study background

The BLISS study was a two-arm randomised controlled trial which was undertaken in Dunedin, New Zealand (population 127,500) over a period of 3.5 years. Participant recruitment began in December 2012, and the final two-year follow-up visits were completed in April 2016. The study aimed to assess the efficacy and acceptability of a modified version of BLW which had been altered to address concerns about potential iron deficiency, growth faltering and choking. This modified version of BLW, which was named the Baby-Led Introduction to Solids, or 'BLISS', approach, had previously been designed and pilot tested by Cameron, Taylor and Heath, with the assistance of paediatricians and speech-language therapists³⁸. The study protocol for the BLISS randomised controlled trial was subsequently developed and published⁹. Ethical approval for the study was granted by the New Zealand Lower South Regional Ethics Committee (LRS/11/09/037) and the study was registered with the Australian New Zealand Clinical Trials 330 Registry ACTRN12612001133820.

3.1.2 Recruitment

Participant recruitment took place between December 2012 and March 2014. All pregnant women who were registered to give birth in the Queen Mary Maternity Centre at Dunedin Public Hospital (>97% of Dunedin births) were sent an information pamphlet and a letter of invitation (Appendix D) to participate in the BLISS study when they were 28 weeks pregnant. Women who were planning home births were given similar information by their Lead Maternity Carer (LMC). The letter included a phone number for an answerphone which mothers could call to leave a message to 'opt-out' if they did not wish to be contacted about the study. Women who had not opted-out within two weeks of receiving the information package were telephoned by a research assistant to explain the study, answer any questions, establish eligibility, and invite participation. If the woman was interested in

participating, a time was made for an individual meeting to give informed written consent to participate (Appendix E).

Women were eligible if they were booked into the study before 34 weeks gestation, were aged 16 years or older, lived within the greater Dunedin area, were not planning to move out of the greater Dunedin area before their child's second birthday, and spoke English or Te Reo Māori. The criteria for post-birth exclusion were birth before 37 weeks gestation or the identification of a congenital abnormality, physical condition or intellectual disability which was likely to affect the infant's feeding or growth.

3.1.3 Sample size

The BLISS study was primarily powered to detect differences in the main study outcome of BMI at 12 months of age, rather than to detect differences in choking or growth faltering⁹. Reference data for sample size calculations were obtained from the ongoing Prevention of Overweight in Infancy (POI) study¹¹⁴ at the University of Otago, which had data on growth in 491 infants aged 0-12 months⁹. Using a mean (standard deviation) of 17.3kg/m² (1.4) and a correlation between repeated measures (BMI at 6 and 12 months) of 0.78, the BLISS study had 80% power at the 5% level of significance to detect a difference in BMI of 0.40kg/m² (25% of a standard deviation) with 85 infants in each group. Sample size was therefore estimated at 200 participants, which allowed for a 15% drop-out for the primary objective. The final number of participants enrolled in the BLISS study was 206.

3.1.4. Randomisation

Randomisation was stratified for parity (first child compared to subsequent child) and education (secondary education only compared to post-secondary education) to ensure that responsiveness to the intervention and study outcomes were not affected by these variables. Following written informed consent, women were randomised to either the intervention (BLISS) or Control group by research staff who were not involved in the collection of outcome measurements; these staff members opened the next consecutive opaque, pre-sealed envelope in the stratum to which the participant belonged and informed the participant which group they had been assigned to.

3.1.5 Study groups

Control group

Families in the Control group received standard government-funded 'Well Child' care from the provider of their choice. No additional intervention was provided by the study. 'Well Child' care is available free of charge to all 0-5 year old infants and children in New Zealand, and typically includes 5 'Postnatal and Transition' visits from the family's Lead Maternity Carer and transitioning Well Child provider (most commonly a Plunket nurse¹¹⁵) between birth and 6 weeks of age, followed by 7 'Infant and Child' visits from the Well Child provider at 8-10 weeks, 3-4 months, 5-7 months, 9-12 months, 15-18 months, 2-3 years and 4 years of age¹¹¹. A General Practitioner visit at 6 weeks of age (when the first immunisation is typically given) is also included in the Well Child schedule. The purposes of the visits are to assess infant growth and development and to provide parents and caregivers with support and health education on a range of topics, including conventional complementary feeding practices¹¹¹.

Intervention (BLISS) group

Participants in this group received both standard "Well Child" care, and the BLISS intervention which included at least 8 additional parent contacts from before birth to 9 months of age. The first five contacts (typically three face-to-face and two phone) were with an International Board Certified Lactation Consultant (IBCLC) antenatally and when the infant was 1 week, 3-4 weeks, 3-4 months and 5 months of age, for support and education around breastfeeding, including the encouragement of exclusive breastfeeding and delaying of the introduction of complementary foods until 6 months of age. The final three contacts were face-to-face visits with a trained researcher at 5.5, 7 and 9 months of age, for the provision of individualized advice and support regarding the introduction of complementary foods (which are typically referred to as "solids" in New Zealand) using the BLISS approach (outlined in Section 3.2 below). Additional support was available throughout the intervention period if required.

3.2 The BLISS approach

3.2.1 Characteristics

The BLISS approach incorporated four key characteristics³⁸:

- 1) The foods offered were to be items which infants could pick up and feed themselves (i.e. a BLW approach to infant feeding was followed)
- 2) One high-iron food was to be offered at each meal
- 3) One high-energy food was to be offered at each meal
- 4) To reduce the risk of choking, all food was to be prepared and offered in a way which was suitable for the infant's developmental age. A list of foods considered to pose a choking risk was provided so that they could be avoided.

As in BLW, families in the BLISS group were encouraged to allow infants to feed themselves all of their complementary food and to choose both the quantity of food which they consumed and the pace at which they ate on each eating occasion. The infant was to be included at family mealtimes and on-demand breast or formula feeding was to be continued throughout the complementary feeding period.

In contrast to BLW, where parents are encouraged to begin complementary feeding when they judge the child to be ready (which is expected to happen at around six months of age)⁵, parents in the BLISS study were advised to begin following the approach as soon as their infant reached 6 months (180 days) of age. Both the early and late introduction of solid foods were discouraged, because of the risk of choking and growth faltering (and iron deficiency) respectively. If parents in the intervention group wished to begin complementary feeding before their infant was 6 months old, they were advised to begin with conventional feeding methods and switch to the BLISS approach when the infant reached six months.

3.2.2. Intervention visits and advice about choking and growth faltering

The 5.5 month BLISS Advice visit was scheduled two weeks before the beginning of the complementary feeding period at 6 months of age in order to allow parents time to

familiarise themselves with the approach (Appendix F). An unblinded, trained research staff member met with each family individually and provided verbal information and written and pictorial resources outlining the approach. The advice and resources relevant to reducing the risk of choking and growth faltering are outlined here and in Appendix G.

Choking

Advice about reducing the risk of choking among infants following BLISS was developed and pilot-tested by Cameron, Heath and Taylor, with the advice of a paediatric speech and language therapist³⁸. Two lists were developed: one which outlined general principles to prevent choking (**Figure 1**) and one which described foods to avoid (**Figure 2**). The trained researcher discussed the lists in detail with each family at the 5.5 month intervention visit, and provided a booklet entitled 'Safety when Starting Food' (Appendix G1) which included both lists. The researcher also explained the differences between choking and gagging and how to manage each event, and how to provide cardiopulmonary resuscitation if necessary, using resuscitation guidelines which had been developed in consultation with The Order of St John (<http://www.stjohn.org.nz/>) during the pilot study. These messages were also reinforced in words and pictures in the 'Safety when Starting Food' booklet.

- | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1. Test foods before they are offered to ensure they are soft enough to mash with the tongue on the roof of the mouth (or are large and fibrous enough that small pieces do not break off when sucked and chewed, e.g. strips of meat) especially in the early months2. Avoid offering foods that form a crumb in the mouth3. Make sure that the foods offered are at least as long as the child's fist, on at least one side of the food4. Make sure the infant is always sitting upright when they are eating – never leaning backwards.5. Never leave your baby alone with food: always have an adult with the child when they are eating.6. Never let anyone except your baby put food into her mouth: the infant must eat at their own pace and under their own control. |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Figure 1. General principles for reducing the risk of food-related choking in BLISS

- | | |
|----|---------------------------------------------------------------------------------------------------------|
| 1. | Foods that you can't mash on the roof of your mouth with your tongue |
| 2. | Very small foods such as nuts, grapes, sweets, and fruit with stones (unless you've removed the stones) |
| 3. | Raw vegetables |
| 4. | Raw apple (whole or sliced) |
| 5. | Under-ripe or hard fruit |
| 6. | Citrus fruits (oranges, mandarins) unless each segment has been peeled |
| 7. | Whole nuts (peanut butter and other nut butters are fine) |
| 8. | Popcorn |
| 9. | Sausages, carrots or any other similar food cut into rounds or 'coins' |

Figure 2: Specific foods to avoid in order to reduce the risk of food-related choking in BLISS

Growth faltering

To reduce the risk of growth faltering, parents in the intervention group were encouraged to offer their infants one high-energy food at each meal⁹. This advice was developed and pilot tested by Cameron, Heath and Taylor³⁸. As a general rule, most foods *except* most fruit (excluding banana and avocado), most vegetables (excluding potato, pumpkin and kumara), plain rice crackers, and clear soups, were classified as high energy foods. This was discussed with each family and two key resources were provided: a booklet titled 'First Foods and Recipes' (Appendix G2) which included detailed information, suggestions and recipes using appropriate food and ingredients for 6-month infants, and an A4 resource sheet entitled 'Everyday Foods from 6 months' (Appendix G3) which displayed a variety of appropriate foods for 6-month old infants. Both resources identified specific foods which met the 'high energy' criteria, as well as items which were high in iron and which were easy to eat.

7 and 9 month BLISS advice visits

At these visits, the trained researchers asked each intervention family how complementary feeding was going. If the family mentioned specific concerns regarding the intervention messages about minimising the risk of food-related choking and growth faltering, the researcher was able to re-iterate the messages or seek further advice from the study team, including the lead researchers, paediatrician and/or speech language therapists.

3.3 Study timeline

The study timeline (**Table 3.1**) identifies the intervention phases and measurement points for both the BLISS and Control groups. The intervention visits (blue) and the outcome measures (yellow) which are relevant to this thesis are highlighted.

Table 3.1 Study timeline for Control and BLISS groups

BLISS	Time-point (age of infant)	Control
Antenatal session	30-40 weeks pregnant	
Baseline questionnaire		Baseline questionnaire
	BIRTH	
Home visit: Lactation Consultant		
Lactation Consultant support phone call (and visit if required)	Week 1	
Breastfeeding and Solids phone questionnaire	Week 3-4	
Lactation Consultant support phone call (and visit if required)	Month 2	Breastfeeding and Solids phone questionnaire
Breastfeeding and Solids phone questionnaire	Month 3.5	
Lactation Consultant support phone call (and visit if required)	Month 4	Breastfeeding and Solids phone questionnaire
BLISS Advice visit	Month 5	
Breastfeeding and Solids phone questionnaire	Month 5.5	
6-month main measurement visit:	Month 6	Breastfeeding and Solids phone questionnaire
Weight, length		6-month main measurement visit:
6-month questionnaire		Weight, length
6-month calendar		6-month questionnaire
BLISS Advice Visit		6-month calendar
Breastfeeding and Solids phone questionnaire	Month 7	
7-month measurement visit:		Breastfeeding and Solids phone questionnaire
Weight		7-month measurement visit:
Microbiota sample		Weight
7-month questionnaire		Microbiota sample
WDR		7-month questionnaire
Breastfeeding and Solids phone questionnaire	Month 8	WDR
8-month measurement visit:		Breastfeeding and Solids phone questionnaire
Weight		8-month measurement visit:
		Weight

8-month questionnaire	Month 9	8-month questionnaire
BLISS		Control
8-month calendar		8-month calendar
BLISS Advice Visit		
Breastfeeding and Solids phone questionnaire		Breastfeeding and Solids phone questionnaire
9-month measurement visit:		9-month measurement visit:
Weight		Weight
9-month questionnaire		9-month questionnaire
Breastfeeding and Solids phone questionnaire		Breastfeeding and Solids phone questionnaire
12-month main measurement visit:		12-month main measurement visit:
Weight, length	Month 12	Weight, length
Microbiota sample		Microbiota sample
Blood test		Blood test
Food preference questionnaire		Food preference questionnaire
12-month questionnaire		12-month questionnaire
WDR		WDR
Breastfeeding and Solids questionnaire		Breastfeeding and Solids questionnaire
24-month main measurement visit:		24-month main measurement visit:
Weight, length		Weight, length
Microbiota sample		Microbiota sample
WDR	Month 24	WDR
24-month questionnaire		24-month questionnaire

3.4 Data collection

The baseline questionnaire was administered to participants by the research assistants who collected informed consent and conducted the study randomisation. All other outcome measurements were collected by trained research assistants who were blinded to group allocation. Questionnaires were used for many of the outcome measures described in this thesis; face-to-face questionnaires were administered to primary caregivers when their infants were 6, 7, 8, 9 and 12 months of age. The questionnaires collected data retrospectively; for example, data for age 6 months was collected in the 7 month questionnaire. In this thesis, the term ‘month’ refers to whole months, so the term ‘6 months’ refers to the time period from 6 months, 0 weeks to the end of 6 months, 3 weeks, and data for other months should be interpreted similarly. Separate ‘Breastfeeding and

Solids' questionnaires were administered to primary caregivers over the telephone retrospectively when infants were 2, 4, 6, 7, 8, 9 and 12 months old.

3.4.1 Baseline questionnaire

The baseline questionnaire was developed using templates from the POI study¹¹⁴ which were modified by the BLISS research team (Appendix H). It was completed by participants at their first appointment, when the mother was approximately 30 weeks pregnant. The questionnaire was split into two sections: 1) demographic information about the infant's parents and household, and 2) details about how the parents planned to feed the infant, and about how they had fed any previous children (if applicable). For ethnicity data, mothers were assigned to mutually exclusive ethnic groups using the 2006 New Zealand National Census question¹¹⁶. Participants who nominated two or more ethnic groups were assigned to a single group using the prioritisation system recommended by Statistics New Zealand, with the order of priority being (from highest to lowest): Māori, Pacific, Asian, Other, New Zealand European¹¹⁶. Following the infant's birth, further demographic information about the infant and mother was collected from the Southern District Health Board, including the infant's date of birth, sex and birthweight, and the mother's parity and New Zealand Deprivation Index (NZDep13) score. The NZDep13 score was used to indicate the level of household deprivation. NZDep13 provides a score from 1 (least deprived) to 10 (most deprived) for each geographical meshblock (geographical units defined by Statistics New Zealand containing a median of approximately 90 people)¹¹⁷.

3.4.2 Choking and gagging

Data about choking and gagging were collected in two ways: retrospectively (by face-to-face questionnaires) and in 'real-time' (using calendars). The calendars, and the relevant parts of the questionnaires, were all generated by BLISS study researchers.

Questionnaires

Choking

Each of the 6, 7, 8, 9 and 12 month face-to-face questionnaires asked the following question about choking:

Has your baby choked on food or drink in the past month?*

☐ No (please go to question 15)

☐ Yes

If yes, how many times?

*in the 6 month questionnaire, 'in the past month' was modified to 'since birth'

If the infant had not choked on food or drink, no further questions about choking were asked. However, if the infant had choked, the caregiver was asked five further questions about the choking incident. If the infant had choked more than once in the last month, the caregiver was asked to answer the following five questions as they applied to the event which they considered to have been the **most serious**:

1 Thinking of the *most serious* choking episode in the past month, which of the following did your baby do?
(Choose as many as apply)

☐ Eyes watered

☐ Pushed tongue out

☐ Coughed

☐ Gasp

☐ Retched

☐ Vomited

☐ Cried

☐ Went silent

☐ Other Please state

2 Thinking again of the *most serious* choking episode in the past month, which of the following happened?
(Choose as many as apply)

☐ Baby resolved it themselves

☐ Parent resolved it

☐ A health professional resolved it

☐ Another person resolved it

☐ A health professional was involved

☐ Baby was admitted to hospital

☐ Other Please state]

3 Thinking again of the *most serious* choking episode in the past month, what was the food or drink responsible (please state whether it was raw or cooked)?

.....

- 4 Thinking again of the *most serious* choking episode in the past month, what form was the food or drink in?
- ☐ Thin liquid
 - ☐ Thick liquid
 - ☐ Puréed
 - ☐ Mashed
 - ☐ Diced
 - ☐ Sliced
 - ☐ Whole
- 5 Thinking again of the *most serious* choking episode in the past month, who fed the baby the food or drink that was responsible?
- ☐ Baby him/herself
 - ☐ Parent
 - ☐ Another adult
 - ☐ Brother or sister
 - ☐ Another child

Gagging

Each of the 6, 7, 8, 9 and 12 month face-to-face questionnaires asked the following question about gagging:

Has your baby gagged on food or drink in the past month?

- ☐ No (please go to question 9)
- ☐ Yes

If yes, how many times? per day OR
 per week OR
 per month

The caregiver was able to respond using the timeframe of their choice, and the study statistician later converted all answers to the number of events per month. No further questions about gagging were included in the questionnaires.

Calendars

Recall bias may be an issue with questionnaires¹¹⁸. Consequently, printed calendars (Appendix I) were designed to assess the frequency of gagging and choking among all study

infants in 'real time' at 6 and 8 months of age. A calendar and 70 coloured sticky dots were given to each primary caregiver at each of the 6 and 8 month measurement visits. At the 6 month visit, detailed verbal explanations of the differences between gagging and choking, and how to identify and deal with each event, were delivered to each main caregiver by the research assistant conducting the appointment. These messages were reinforced in writing on the calendar, which also included written and pictorial information about how to provide cardiopulmonary resuscitation (CPR). Caregivers were instructed to place two sticky dots on the calendar each day once the infant had finished eating and drinking: one in a space which indicated whether or not they had gagged that day, and the other in a space which indicated whether or not they had choked (in order to differentiate between days when there was no choking and days when data were not recorded). If the caregiver indicated that the child had gagged, no further information was required. However, if the caregiver indicated that the child had choked, they were instructed to answer the following four questions in the spaces provided on the calendar: 1) *What was the food?* 2) *What form was it in? (thin liquid, thick liquid, purèed, mashed, diced, whole)* 3) *Was baby feeding themselves? (yes/no)* 4) *What happened?* Each calendar was to be filled out on a daily basis until the infant's next measurement visit (at either 7 or 9 months of age), at which time it was collected by a research assistant.

3.4.3 Parental feeding practices

To identify whether parents in each study group employed safe feeding practices with their infants, the following questions were asked in the 7, 8, 9 and 12 month face-to-face questionnaires:

How often do you, or another adult, sit with your child when they're eating?

- ☐ Never
- ☐ Occasionally
- ☐ About half the time
- ☐ Almost always
- ☐ Always

Where does your baby sit to eat their solids? (tick all that apply)

- ☐ Highchair

- ☐ Chair attached to table
- ☐ Baby sized chair on floor
- ☐ Floor
- ☐ Someone's knee
- ☐ Other Please state

3.4.4 Adherence to a baby-led approach

To assess adherence to a baby-led approach, the following question was asked in the 'Breastfeeding and Solids' telephone questionnaires which were administered by a BLISS Research Assistant when each infant was 2, 4, 6, 7, 8, 9 and 12 months old:

How has *[child's name]* been fed their solids in the **past week**?

Note: "Baby fed themselves" means that baby picks up the food, puts it in their mouth and appears to swallow at least some.

- ☐ Fed by adult
- ☐ Mostly fed by adult, some baby feeding themselves
- ☐ About half spoon feeding by adult and half baby feeding themselves
- ☐ Mostly baby feeding themselves, some adult feeding
- ☐ Baby feeding themselves

At each time-point, infants who were always or mostly fed by an adult were defined as not adherent to a baby-led approach. Those who were about half fed by an adult and about half self-fed were defined as partially adherent to a baby-led approach, while those infants who were always or mostly self-fed were defined as adherent.

3.4.5 Infant exposure to foods posing a choking risk: weighed diet records

Three-day weighed diet records (WDR, Appendices J1-J4) were completed by the primary caregiver for each infant when they were 7 and 12 months of age. The WDRs were used for many research purposes within the BLISS study; for this thesis, they were used to determine infant exposure to foods thought to pose a choking risk.

Three documents were included in the WDR; each had been developed and pilot tested by Claire Schramm (MDiet student)¹¹⁹. The primary document was the 'BLISS Food Diary'

(Appendix J1) which had been developed by modifying the WDR template used in the Toddler Food Study¹²⁰ to include measurements of the level of infant self-feeding and the form (consistency) of the food offered to infants. At the 7 and 12 month measurement visits, the primary caregiver was given the BLISS Food Diary and two accompanying documents: the 'Away from Home Food Diary' (Appendix J2) and the 'Childcare Food Diary' (Appendix J3). It was expected that most recording would be completed in the 'BLISS Food Diary', while the 'Away from Home Food Diary' booklet was only to be used when the infant and caregiver were not at home, and the 'Childcare Food Diary' was to be completed by childcare providers when the infant was in their care. Between the three diary documents, it was expected that the weighed diet records would capture detailed information about all of the food and drink offered to and consumed by each infant over the three days of recording. The BLISS Food Diary included spaces to record the time that each food or drink was offered, the type, amount (in grams), preparation methods and final consistency of each food and drink and details about leftovers, including their overall weight (in grams) on each eating occasion. It also included space for primary caregivers to record recipes and to answer further questions about supplement use and about how the items offered to the infant that day compared to those offered to the rest of the family. The 'Away From Home Food Diary' and the 'Childcare Food Diary' recognised that it could be difficult and/or time-consuming for parents and caregivers to weigh foods which were consumed outside the home. As a result, in these diaries it was acceptable for participants to include estimates, rather than exact weights, of the amount of food consumed by the infant.

Each family was randomly assigned to three non-consecutive days of weighed diet recording (two weekdays and one weekend day) over a three-week period when infants were 7 and 12 months old. On the day of each infant's 7 and 12 month measurement appointments, BLISS research assistants used a Microsoft Excel spreadsheet (on which each day of the week was represented an equal number of times across the BLISS and Control groups) to assign the participant's days of recording. The first day of the WDR was always the day immediately after the measurement appointment. At the appointment, each caregiver received a set of dietary scales (Salter Electronic, Salter Housewares Ltd, Tonbridge, UK) which were accurate to $\pm 1\text{g}$, and two spare batteries along with the paper documents. The research assistant provided detailed verbal instructions about how to complete the WDR,

and a written reminder of these instructions was also provided, in the form of a laminated example of a completed day of weighed diet recording which was to be stuck on the family's refrigerator (Appendix J4). For the identification of foods thought to pose a choking risk to infants, the following instructions about how to categorise food by consistency were particularly pertinent to this thesis: *'purèed food has been blended together using a machine to make a smooth consistency', 'mashed food has been mashed by hand to a lumpy consistency', 'diced food has been chopped into small pieces, needing a spoon to eat it' and 'whole food can include food cut into more manageable portion sizes, such as toast fingers'.*

The day after the first day of recording, a BLISS researcher telephoned each family to remind the caregivers to complete the record and to answer any questions. When the WDRs were returned to the BLISS office, they were checked by a New Zealand registered dietitian, who then clarified any misunderstandings with the caregiver within a few days of record completion.

3.4.6 Infant weight and length

Infant weight was measured at 6, 7, 8, 9, and 12 months using scales (Seca, Model 334, Hamburg, Germany) while infant length was measured at 6 and 12 months using a rollameter (Rollameter 100c length board, Harlow Healthcare, UK). Both the scales and the rollameter were calibrated prior to each measurement session. Infants were measured while wearing a standard nappy of known weight which was provided to the parent, and a singlet top. All measurements were taken in duplicate following WHO protocols⁸⁵. As per the study protocol (Appendix K) if duplicate measures at any one time-point differed by more than 0.1kg for weight, or more than 0.7cm for length, a third measurement was taken and an average of the measures was then recorded. In the case of three different measurements, the two closest were averaged; if the measurements were equidistant, the median value was used.

3.5 Data coding and entry

3.5.1 Questionnaire data

Following their administration to participants, the 6, 7, 8, 9 and 12 month face-to-face questionnaires (which were initially collected on paper) were uploaded onto the BLISS database by research staff. Following the completion of all 12-month measurement visits, the Candidate double-checked all of the online data entry against the hard copies.

3.5.2 Calendar data

Following completion of all 9-month measurement visits (when all of the 8-month calendars had been collected), the Candidate developed a Microsoft Excel spreadsheet on which to enter the number of gagging and choking events per infant, per day of diet recording. The Candidate then transferred all information from the calendars to the spreadsheet for statistical analysis.

3.5.3 Weighed diet records

Development of list of foods thought to pose a choking risk to infants

To determine infant exposure to foods thought to pose a choking risk, a list of such foods was required for comparison with each WDR. The Candidate developed a new list (**Figure 3**) to be used for this purpose, because in the time between the development of the list of foods to avoid in BLISS (Figure 2) and the beginning of this project, the NZ MOH had revised their guidelines about foods which pose a choking risk to infants and young children (Appendix A)¹. To ensure the development of a comprehensive and up-to-date list, the current recommendations of five different groups^{1,38, 121-123} were compared. Any food item which was listed as a choking risk by four or five of the groups was automatically included in the final list of foods thought to pose a choking risk. Any item over which there was a lack of agreement between lists, or which the Candidate had queries about, was discussed with a paediatric speech language therapist with experience in choking in children before a final decision was made. The rationale behind the creation of this list is fully outlined in Appendix L.

Battered fish
Berries
Chewing gum
Corn
Corn chips
Crisps
Dried fruit
Hard crackers
Marshmallow
Meat
Peas
Popcorn
Sausages and similar products
Raw apple
Raw pineapple
Raw vegetables
Baby rusks
Seeds
Small/hard/sticky candy
Whole cherries
Whole cherry tomatoes
Whole grapes
Whole nuts

Special considerations were required for some items. These are outlined in full in Appendix L.

Figure 3. List of foods thought to pose a choking risk to infants developed by the Candidate

Finally, the Candidate developed two Microsoft Excel spreadsheets (one for 7 month data and one for 12 month data) in which all foods thought to pose a choking risk to infants were listed. The Candidate examined each day of diet recording completed by each participant, and entered all foods which were thought to pose a choking risk and which had been offered to the infant onto the relevant spreadsheet. The spreadsheets were then used for statistical analysis of infant exposure to foods thought to pose a choking risk.

3.5.4 Identification of growth faltering

Infant weight and height measurements were entered into the BLISS database by a BLISS research assistant as soon as possible after each measurement visit. The measurements were also entered into the Apple i-phone STAT GrowthCharts WHO Lite app (Austin Physician Productivity LLC, Version 3.2) which calculated infant BMI, BMI-for-age z scores, and weight-for-age z-scores at the time-points outlined in Table 3.2. These figures were then entered into the BLISS database, which calculated the differences in infant weight (grams), infant weight-for-age z-scores, and BMI-for-age z-scores at the relevant time-points in **Table 3.2**.

Table 3.2 Measures of infant growth calculated between 6 and 12 months of age

Age	Growth Measures
6 months	Weight-for-age z-score
	Infant BMI
	BMI-for-age z-score
7 months	Weight-for-age z-score
	Weight difference (grams) between 6 and 7 months
	Difference in weight-for-age z-score between 6 and 7 months
8 months	Weight-for-age z-score
	Weight difference (grams) between 7 and 8 months
	Difference in weight-for-age z-score between 7 and 8 months
	Difference in weight-for-age z-score between 6 and 8 months
9 months	Weight-for-age z-score
	Weight difference (grams) between 8 and 9 months
	Difference in weight-for-age z-score between 8 and 9 months
	Difference in weight-for-age z-score between 6 and 9 months
12 months	Weight-for-age z-score
	Difference in weight-for-age z-score between 6 and 12 months
	Infant BMI
	BMI-for-age z-score
	Difference in BMI-for-age z-score between 6 and 12 months

For the purposes of this thesis, and for the main outcomes of the BLISS study, **growth faltering was defined as a weight deceleration of more than 1.34 of a z-score from 6 to 9 months of age**. This equated to the downwards crossing of two percentile lines on the WHO-CGS, where the major centile lines are two-thirds of a standard deviation apart⁹.

In order to identify any potential growth problems as early as possible, infant measurements at each time-point were also compared against five ‘growth triggers’, as outlined in **Figure 4** below. Meeting a growth trigger was an indication that an infant was potentially at risk of growth faltering.

Trigger 1: At 6 months of age (i.e. first BLISS study measurement), an infant's weight-for-age z-score being below (i.e. more negative than) -2

Trigger 2: At 6 months of age (i.e. first BLISS study measurement), an infant's BMI-for-age z-score being below (i.e. more negative than) -2

Trigger 3: No increase in an infant's weight across successive measurements from 6 to 9 months of age (i.e. at 6-7, 7-8, 8-9, 6-8, or 6-9 months)

Trigger 4: A decrease in an infant's weight-for-age z-score of more than 1 between successive measurements from 6 to 12 months of age (i.e. at 6-7, 7-8, 8-9, 6-8, 6-9, 9-12, or 6-12 months)

Trigger 5: A decrease in an infant's BMI-for-age z-score of more than 1 between 6 and 12 months of age

Figure 4: Definitions of the five BLISS study growth triggers

When an infant met any of the growth triggers outlined in Figure 4, one of the study paediatricians (who was responsible for growth faltering intervention if that was needed) was contacted by a BLISS research assistant, who provided information about the infant's growth history and whether the infant had been unwell since their last measurement visit. The paediatrician considered whether the information indicated that the infant was potentially at risk of growth faltering before advising the research assistant of the next step in the process. He then made one of the three following recommendations:

1. Continue with the standard study measurement schedule, but provide the study paediatrician with the results of the infant's next scheduled measurement
2. Schedule an 'extra measurement' (i.e. a measurement which was additional to the standard study measurement schedule) in a few weeks (the study paediatrician was to suggest an appropriate time-frame for the extra measurement) and notify the study paediatrician of the outcome so that the infant's growth trajectory could be re-evaluated
3. Send an official referral to the study paediatrician, so that the infant could be booked into and assessed in his outpatient clinic at Dunedin Public Hospital.

3.5.5 Adverse events

Adverse events were defined as any untoward or unfavourable medical occurrence in a participant, including any abnormal sign, symptom or disease, temporally associated with the participant's participation in the research, whether or not it was considered to be related to the participant's participation in the BLISS study^{9,124}. Choking, growth faltering and iron deficiency were all recognised as potential adverse events in the BLISS study and were actively monitored. Further information on adverse events was collected passively throughout the study, i.e. participant concerns were collated as they were spontaneously reported to researchers. A serious adverse event was defined as any adverse event which resulted in death, was life-threatening, required inpatient hospitalisation, resulted in persistent or significant disability or incapacity, or which could potentially have jeopardized the participant's health and possibly have required medical or surgical intervention to prevent one of the other outcomes listed above^{9,124}.

3.6 Statistical analysis

All data were analysed according to modified intention to treat, and all statistical analysis was conducted using Stata13 (StataCorp, College Station, TX). A *P*-value <0.05 was considered to indicate statistical significance.

Choking and gagging

Inferential statistics: Poisson regression with robust standard errors was used to compare the number of children in the Control and BLISS groups who choked and gagged (Tables 4.2 and 4.7)¹²⁵. Poisson regression was also used to compare the number of children offered foods posing a choking risk in the two groups (Tables 4.11 and 4.12). Negative binomial regression was used to compare the number of gagging events per infant in the two groups (Table 4.8). Ordered logistic regression was used to compare the supervision of infant mealtimes by parents in the BLISS and Control groups (Table 4.9). A chi-squared test was used to compare eating locations in the BLISS and Control groups (Table 4.10).

Descriptive statistics

Due to limited numbers of choking events at each time-point in the study, it was not possible to generate inferential statistics for the 129 parent-defined ‘most serious’ choking episodes in the BLISS and Control groups. Instead, the characteristics of the 129 events in the BLISS and Control groups were described in detail (Tables 4.4 and 4.5). The number of events per adherence category was also described (Table 4.6).

Growth faltering

Data about growth faltering were examined descriptively, due to the absence of growth faltering, and to the limited numbers of infants meeting growth triggers at each time-point (Tables 4.13, 4.14, 4.15).

4. Results

4.1 Participant demographics

The characteristics of infants, mothers and families in the BLISS study are shown in **Table 4.1**. A total of 206 families agreed to participate (23% response rate, not including exclusions and unsuccessful attempts at contact). At baseline (late pregnancy), mothers had a mean age of 31.3 years, which is slightly older than the national median age of 30.2 years¹²⁶ for women who are giving birth. In both study groups, mean pre-pregnancy BMI was lower than the national average for women aged 25-34 years in New Zealand (27.6 kg/m²)¹²⁷. Mothers were well educated, with 52.5% of women in the Control group and 44.8% of mothers in the BLISS group having a university degree, compared to 28% of the adult New Zealand population¹²⁸. The NZDep13¹¹⁷ was used to measure household deprivation; in the general population, it would be expected that 30% of households would have a deprivation score of 1-3 (least deprived), 40% a score of 4-7, and 30% a score of 8-10 (most deprived). In the study population, nearly 30% of participants in each group scored 1-3, but higher percentages (48.5% in the Control group and 50.5% in the BLISS group) scored 4-7 and lower percentages (22.8% Control and 20.0 BLISS) scored 8-10, indicating that the study population was less deprived than the general New Zealand population¹¹⁷.

The infant participating in BLISS was the first child in approximately 41% of families and the birth weight and ethnic distribution were similar in the two groups. By contrast, there were more female infants (59%) in the BLISS group than in the Control group (47.5%). The ethnic distribution of the infants was similar to the ethnic distribution of the New Zealand population as a whole (74.6% New Zealand European, 15.6% Māori, 7.8% Pacific and 12.2% Asian)¹²⁹, while the ethnic distribution of the mothers compared more closely to the ethnic distribution of the population in the Otago region (89.1% New Zealand European, 7.5% Māori, 2.0% Pacific, 5.2% Asian)¹³⁰.

Table 4.1. Baseline characteristics of mothers, infants and households in the Control and BLISS groups

Characteristic ¹	Control	BLISS
N	101	105
Maternal age (years) ² (mean, SD)	31.3 (6.2)	31.3 (5.0)
Pre-pregnancy BMI ³ (mean, SD)	25.6 (6.2)	25.9 (6.3)
Maternal education		
<i>School only</i>	29 (28.7)	34 (32.4)
<i>Post-secondary</i>	19 (18.8)	24 (22.9)
<i>University</i>	53 (52.5)	47 (44.8)
Maternal employment		
<i>Not employed</i>	33 (32.7)	20 (19.0)
<i>Part-time</i>	27 (26.7)	36 (34.3)
<i>Full-time</i>	41 (40.6)	49 (46.7)
Parity		
<i>First child</i>	42 (41.6)	43 (41.0)
<i>Two children</i>	32 (31.7)	43 (41.0)
<i>3 or more children</i>	27 (26.7)	19 (18.0)
Marital status		
<i>Single</i>	9 (8.9)	8 (7.6)
<i>Married/partner</i>	92 (91.1)	97 (92.4)
Maternal ethnicity		
<i>New Zealand European and Others</i>	85 (84.2)	83 (79.0)
<i>Māori or Pacific</i>	10 (9.9)	15 (14.1)
<i>Asian</i>	6 (5.9)	7 (6.7)
Household Deprivation ⁴		
<i>1-3 (Low)</i>	29 (28.7)	31 (29.5)
<i>4-7</i>	49 (48.5)	53 (50.5)
<i>8-10 (High)</i>	23 (22.8)	21 (20.0)
Infant birth weight (g) ⁵	3534 (490)	3517 (439)

	Control	BLISS
Infant sex ⁶		
<i>Male</i>	53 (52.5)	43 (41.0)
<i>Female</i>	47 (47.5)	62 (59.0)
Infant ethnicity		
<i>New Zealand European</i>	70 (69.3)	75 (71.4)
<i>Māori or Pacific</i>	23 (22.8)	22 (21.0)
<i>Asian</i>	8 (7.9)	8 (7.6)

¹Data expressed as n(%) except where indicated.

Data missing for ²1, ³7, ⁵9 and ⁶1 participants.

⁴ NZDep13 is the New Zealand Deprivation Score, which is a measure of relative socio-economic deprivation with a scale from 1-10 where 10 is the most deprived¹¹⁷

4.2 Choking

Table 4.2 displays the number and percentage of infants who choked at least once at each time-point, by study group. At each time-point, some episodes of choking were observed in both study groups, with the percentage of children who choked at any time-point ranging from 7.1% (Control group, 0-<6 months, questionnaire data) to 25.3% (Control group, 6 months, calendar data). However, there were no significant differences between the groups at any of the time-points, in either the data collected retrospectively by questionnaire or the ‘real-time’ data obtained by the calendars.

In total, 894 questionnaires were collected between birth and 12 months of age, with at least one episode of choking being reported in 129 (14.4%) questionnaires. Because missing data were apparent at each time-point, a subset of participants with complete data from 6 to 8 months of age was identified to determine the rate of choking in a complete dataset. Six to 8 months of age was considered to represent the beginning of the complementary feeding period, when higher rates of choking may be expected due to infants being inexperienced with solid food. A total of 170 infants (80 Control, 90 BLISS) were found to have completed all three questionnaires between 6 and 8 months of age (510 questionnaires in total). The percentages of these infants who had choked at least once

between 6 and 8 months of age were almost identical in the two study groups: 28 (35%) infants in the Control group and 31 (34%) of infants in the BLISS group.

Table 4.2 *Number of infants in the Control and BLISS groups who choked each month, by questionnaire and calendar*¹

<i>Age</i> ²	<i>Control</i>	<i>BLISS</i>	<i>RR (95% CI)</i> ³	<i>P</i> ⁴
<i>Choked at least once, by questionnaire</i> ⁵				
0 to < 6 months	6/85 (7.1%)	8/96 (8.3%)	1.10 (0.39, 3.10)	0.856
6 months	19/88 (21.6%)	17/94 (18.1%)	0.86 (0.48, 1.54)	0.607
7 months	7/83 (8.4%)	11/91 (12.1%)	1.31 (0.53, 3.21)	0.559
8 months	16/88 (18.2%)	14/95 (14.7%)	0.78 (0.40, 1.52)	0.463
11 months	13/81 (16.0%)	18/93 (19.4%)	1.21 (0.63, 2.31)	0.569
<i>Choked at least once, by Calendar</i>				
6 months	20/79 (25.3%)	14/86 (16.3%)	0.67 (0.37, 1.23)	0.201
8 months	14/74 (18.9%)	14/78 (17.9%)	0.94 (0.48, 1.87)	0.869

¹ Data expressed as number of participants who choked/number of participants with data (%).

² Months refer to whole months, unless stated otherwise, so that '8 months' refers to 8.0 to 8.9 months of age.

³ Relative risk in BLISS participants compared to Control participants. Data were analysed using Poisson regression with robust standard errors, controlling for maternal education and parity (the stratification variables used at randomization).

⁴ P value is for relative risk in BLISS participants compared to Control participants, controlling for maternal education and parity (the stratification variables used at randomization).

⁵ Questionnaire data were collected retrospectively at the beginning of the next month. For example, the data reported here for age 6 months were collected in the 7 month questionnaire.

Table 4.3 displays the frequency of choking events among the infants who choked one or more times at each time-point. In total, 199 (100 Control and 99 BLISS) events were reported. In 60 (46.5%) of the 129 questionnaires, the infant was reported to have choked only once at the relevant time-point; in the other 69 questionnaires, the total number of choking events per month ranged from 'unknown' to 9. However, only three participants were reported to have choked ≥ 3 times within one month. Two of these were infants in the Control group; one choked 6 times and one choked 9 times within the first six months, while the third was a BLISS participant who choked 8 times at 6 months of age. Although the number of choking events per time-point was too small to allow for statistical tests between

the study groups, the descriptive findings outlined do not suggest that infants in the BLISS group choked more frequently than infants in the Control group.

Table 4.3 Frequency of choking events among infants who choked at least once at <6, 6, 7, 8, 9 and 11 months of age¹

Age in months												
	0 to <6 months		6 months		7 months		8 months		11 months		Total	
	(n=14)		(n=36)		(n=18)		(n=30)		(n=31)			
Frequency of events	Control (n=6)	BLISS (n=8)	Control (n=19)	BLISS (n=17)	Control (n=7)	BLISS (n=11)	Control (n=16)	BLISS (n=14)	Control (n=13)	BLISS (n=18)	Control	BLISS
1	3 (50)	6 (75)	10 (53)	7 (41)	5 (71)	7 (63)	6 (38)	7 (50)	4 (31)	5 (28)	28	32
2	1 (17)	0	3 (16)	4 (23)	1 (14)	1 (9)	3 (19)	3 (21)	2 (15)	2 (11)	20	20
3	0	0	1 (5)	3 (18)	0	0	1 (6)	3 (21)	1 (8)	1 (6)	9	21
4	0	0	0	0	0	0	2 (12)	0	0	0	8	0
5	0	0	0	0	0	0	1 (6)	0	0	0	5	0
6	1 (17)	0	0	0	0	0	0	0	0	0	6	0
8	0	0	0	1 (6)	0	0	0	0	0	0	0	8
9	1 (17)	0	0	0	0	0	0	0	0	0	9	0
Unknown ²	0	2 (25)	5 (26)	2 (12)	1 (14)	3 (27)	3 (18)	1 (7)	6 (46)	10 (56)	15	18
Total # of events	20	8	24	34	8	12	31	23	17	22	100	99

¹Data expressed as n(%). For example, at 0 to <6 months of age, 6 infants in the Control group choked, of whom 3 (50%) choked once, while 1 choked twice.

²'Unknown' indicates that in the questionnaire, the parent indicated that the infant had choked during that time period, but did not give an answer to the question 'how many times has your infant choked?'. In the total count of events in this table, the 'unknown' cases were counted as one event.

Table 4.4 describes the characteristics of the 129 ‘most serious choking events’ reported in the questionnaires at each time-point. As the number of events at each time-point was too small to allow for statistical comparisons between study groups, only descriptive findings are provided here. The infant fed themselves in most (n=109, 84.5%) of these 129 episodes (60 BLISS, 49 Control). In all other instances the infant had been fed by a parent, with two exceptions: one infant in the Control group was given a jellybean by a sibling, and there was another event where the mother of a Control infant could not recall who had fed the infant.

In 9 (7%) cases, the food responsible for the choking episode was actually a liquid. Three infants in the BLISS group, and two in the Control group, choked on a liquid before 6 months of age. There were three further episodes of choking on liquids in the Control group at 7 months of age, and one other episode in an 11-month old infant in the BLISS group. There was also one episode of choking on puréed food, and several episodes of choking on mashed, diced and sliced foods, throughout the study period. However, in over half (n=75 (58%)) of the 129 most serious events, food of a ‘whole’ consistency was responsible. Forty of these 75 choking episodes occurred among BLISS participants and 35 among Control participants.

Of the most serious episodes of choking, 51% were resolved by the infant themselves, 37% were resolved by a parent, and the remaining 12% of cases were resolved by another person, or by a combination of people (for example, there were 11 instances in which the infant and parent jointly resolved the choking episode). There was one episode where a health professional became involved but the infant was not admitted to hospital, and there were two episodes where both a health professional was involved and the infant was admitted to hospital. The first episode involved an eight month old female in the BLISS group. The father of the infant had placed a piece of steamed apple directly in her mouth for her to suck on; she had subsequently inhaled it. The parents tried back blows to dislodge the apple and called the ambulance, which arrived just as the item was dislodged by the infant. The parents described the infant’s breathing as laboured and wheezy during the event, with the infant clearly in distress. She was transported to hospital for an examination and x-rays, which did not find anything of concern, nor result in an inpatient hospitalisation. The other two episodes (one Control, one BLISS) both resulted in inpatient hospitalisation,

and therefore were defined as serious adverse events. The episode in the Control group involved a 6-month infant who vomited after drinking a bottle of milk, then aspirated the vomit, while the episode in the BLISS group involved an infant who choked on infant formula before he was six months old.

Table 4.4 Characteristics of the 129 parent-defined 'most serious' choking episodes, by age¹

	0 to < 6 months		6 months		7 months		8 months		11 months	
	Control	BLISS	Control	BLISS	Control	BLISS	Control	BLISS	Control	BLISS
	(n=85)	(n=96)	(n=88)	(n=94)	(n=83)	(n=91)	(n=88)	(n=95)	(n=81)	(n=93)
Choked at least once	6 (7.1)	8 (8.3)	19 (21.6)	17 (18.1)	7 (8.4)	11 (12.1)	16 (18.2)	14 (14.7)	13 (16.0)	18 (19.4)
Who fed the infant?										
<i>Infant</i>	4 (66.7)	5 (62.5)	15 (78.9)	16 (94.1)	6 (85.7)	1 (90.9)	14 (88.0)	13 (92.9)	10 (76.9)	16 (88.9)
<i>Parent</i>	2 (33.3)	3 (37.5)	3 (15.8)	1 (5.9)	1 (14.3)	1 (9.1)	1 (6.5)	1 (7.1)	3 (23.1)	2 (11.1)
<i>Sibling</i>	0 (0.0)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Missing</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.5)	0 (0.0)	0 (0.0)	0 (0.0)
What form was the food in?										
<i>Liquid</i>	2 (33.3)	3 (37.5)	3 (15.8)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
<i>Puréed</i>	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.9)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Mashed</i>	1 (16.7)	0 (0.0)	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Diced</i>	0 (0.0)	0 (0.0)	2 (10.5)	0 (0.0)	1 (14.3)	1 (9.1)	2 (12.5)	2 (14.3)	1 (7.7)	3 (16.7)
<i>Sliced</i>	1 (16.7)	3 (37.5)	5 (26.3)	4 (23.5)	1 (14.3)	3 (27.3)	1 (6.25)	3 (21.4)	4 (30.8)	3 (16.7)
<i>Whole</i>	2 (33.3)	2 (25.0)	8 (42.1)	12 (70.6)	5 (71.4)	7 (63.6)	12 (75.0)	9 (64.3)	8 (61.5)	10 (55.4)
<i>Missing</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.25)	0 (0.0)	0 (0.0)	1 (5.6)
Who resolved the episode? ²										
<i>Infant</i>	4 (66.7)	4 (50)	12 (63.2)	5 (29.4)	5 (71.4)	4 (36.4)	13 (81.3)	7 (50.0)	11 (84.6)	12 (66.6)
<i>Parent</i>	2 (33.3)	6 (75)	9 (47.4)	12 (70.6)	1 (14.3)	7 (63.6)	5 (31.3)	8 (57.1)	5 (38.5)	6 (33.3)
<i>Health professional</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Another person</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (5.6)
Additional involvement ³										
<i>Health professional</i>	0 (0.0)	1 (12.5) ⁴	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1) ⁶	0 (0.0)	0 (0.0)
<i>Admitted to hospital</i>	0 (0.0)	1 (12.5) ⁴	1 (5.3) ⁵	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
<i>Other</i>	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6) ⁷

¹ Data presented as n(%).

² Participants were able to choose more than one response and therefore some totals add to more than 100%.

³ Additional involvement did not resolve the episode but was associated with it.

⁴ The infant choked on infant formula; he and a parent jointly resolved the episode but a health professional then became involved and the infant was admitted to hospital.

⁵ The infant vomited after drinking a bottle of milk, then aspirated some vomit and was consequently admitted to hospital.

⁶ The infant choked on a piece of steamed apple that a parent had placed directly in her mouth. The infant resolved the issue herself as the ambulance arrived and was transported to hospital but did not require admission.

⁷ The choking episode happened at daycare and was not observed by the parent who completed the questionnaire.

Table 4.5 illustrates the foods which infants choked on at each time-point, and the percentage of these foods that were items thought to pose a choking risk, as listed in Figure 3 and Appendix L. Overall, only 23% of the foods choked on were foods thought to pose a choking risk, with the proportions in the two groups appearing to be similar (25% in the Control group and 21% in the BLISS group).

It is important to note that some items did not strictly fit the criteria described in the list of foods thought to pose a choking risk and therefore were not counted here, but comments within the questionnaires suggest that they were served in a way which did pose a choking risk. For example, one of the servings of steak choked on by a BLISS participant at 6 months of age was described as being of puréed texture, but the comments indicated that the purée contained 'stringy bits'. Similarly, another child in the BLISS group choked on mango at 6 months of age and the parent commented that the mango 'had a stringy bit' which got stuck in the child's 'throat' (airway).

Table 4.5 Foods responsible for the 129 parent-defined 'most serious' episodes of choking

Age (months) ¹	Control ²	Number of foods thought to pose a choking risk ^{3 4}	BLISS ²	Number of foods thought to pose a choking risk ^{3 4}
0 to < 6 (n=14)	Banana ⁶ , breast milk (n=2), carrot ⁶ , chocolate, steak	0/6 (0%)	Banana ⁵ (n=2), breast milk, cheese, infant formula (n=2), parsnip ⁶ , toast	0/8 (0%)
6 (n=36) ⁷	Biscuits ⁸ (n=2), carrot ⁶ , cheese, chicken*, cruskit, feta, jellybean*, milk, mince, potato (n=4), rusk (n=2)** , toast, water (n=2)	4/19 (21%)	Banana ⁵ , beef, cauliflower ⁶ , cheese (n=2), hot potato chip, kumara ⁶ , mandarin ⁵ , mango, meatballs, pikelet, potato (n=2), steak (n=2), toast (n=4)	0/19 (0%)
7 (n=18) ⁷	Apple ^{5*} , banana ⁵ , biscuit ⁸ , broccoli ⁶ (n=2), cauliflower ⁶ , cruskit, mandarin ⁵ , strawberry ⁵ , toast	1/10 (10%)	Banana ⁵ (n=2), broccoli ⁵ , cracker*, crisps*, cucumber ^{5*} , mince, pork, potato patty, toast (n=2), watermelon ⁵	3/12 (25%)
8 (n=30) ⁷	Apple ⁵ (n=3)***, biscuits ⁸ (n=2), bread, bread bun, carrot ⁶ , cruskit, cucumber ^{5*} , 'fish* and chips', pineapple ^{5*} , tomato*, toast (n=2), unknown (n=2)	7/17 (41%)	Apple ^{5*} , apple ⁶ , bacon*, banana, carrot ³ , cheese, cracker*, cucumber*, hashbrown, hot potato chip, mandarin, meatloaf, pineapple ^{5*} , potato, strawberry, sausage (n=2)**	7/17 (41%)
11 (n=31) ⁷	Apple ^{5*} , banana ⁵ , brisket*, capsicum ⁵ , carrot ^{5*} , carrot, chicken*, corn cake, cracker*, green bean ⁶ , peach ⁵ , steak, toast, unknown/non-food item (n=2)	5/15 (33%)	Banana ⁵ , carrot ⁶ , chicken*, chicken, cucumber ^{5*} , kiwifruit ⁵ , mandarin ⁵ , orange ⁵ , popcorn* rice cracker ^{5*} , sausage*, snack bar, unknown/non-food item (n=3), water	5/16 (31%)
Total		17/67 (25%)		15/72 (21%)

¹⁻⁸Footnotes outlined overleaf.

¹The n in this column represents the total number of choking events which were reported in the questionnaires at the relevant time-point

²Where n is not explicitly stated, n=1

³Data presented as n(number of foods thought to pose a choking risk/total number of foods responsible for choking events at this point) (%).

⁴Foods which pose a choking risk are outlined in Figure 3 and Appendix L and indicated in this table with *. Multiple * are present when a food which poses a choking risk has been responsible for more than 1 choking episode, i.e. rusk (n=2)** indicates that two rusks, both of which posed a choking risk, were responsible for two separate episodes of choking

⁵indicates that the named fruit or vegetable was served raw. In some cases the parent did not indicate whether a specific fruit or vegetable was served cooked or raw and therefore no footnote number is included.

⁶indicates that the named fruit or vegetable was served cooked. In some cases the parent did not indicate whether a specific fruit or vegetable was served cooked or raw and therefore no footnote number is included.

⁷The number of foods listed exceeds the number of choking episodes for that month. This is because when asked to name the food responsible for the 'most serious' choking incident, some parents named more than one item.

⁸The 'biscuits' described were all considered to be dissolvable in the mouth and hence quite different from crackers, which were counted separately.

Table 4.6 displays the number of choking events per month by level of adherence to a baby-led approach to complementary feeding. This analysis was conducted because other data indicated that at each time-point, a minority of participants were not adherent to the approach which they were randomised to, therefore possibly confounding the results when they were presented by study group. Although the number of infants who choked at each time-point was too small to allow for statistical comparisons, this table suggests that the percentage of infants who actually choked at each time-point was similar regardless of the degree of adherence to the BLISS approach. For example, at 6 months of age, 20.0%, 23.1%, and 20.0% of infants in the 'Not baby-led', 'Partially baby-led' and 'Baby-Led' categories respectively had choked at least once.

Table 4.6 Number of infants who choked per time-point, by level of adherence to a baby-led approach to complementary feeding^{1,2}

	Not baby-led	Partially baby-led	Baby-led	Not yet started solids	Incomplete data
0 to < 6 months					
<i>Total n</i> ³	69 (33.5)	14 (6.8)	51 (24.8)	35 (17.0)	37 (17.9)
<i>Choked n</i> ⁴	4 (5.8)	3 (21.4)	3 (5.9)	-	4 (10.8)
6 months					
<i>Total n</i>	60 (29.1)	26 (12.6)	75 (36.4)	0 (0.0)	45 (21.9) ⁵
<i>Choked n</i>	12 (20.0)	6 (23.1)	15 (20.0)	-	3 (6.7)
7 months					
<i>Total n</i>	45 (21.9)	39 (18.9)	89 (43.2)	0 (0.0)	33 (16.0)
<i>Choked n</i>	3 (6.7)	5 (12.8)	8 (8.9)	-	2 (6.1)
8 months					
<i>Total n</i>	42 (20.4)	40 (19.4)	95 (46.1)	0 (0)	29 (14.1) ⁶
<i>Choked n</i>	8 (19.0)	8 (20.0)	12 (12.6)	-	2 (6.9)
11 months					
<i>Total n</i>	25 (12.1)	39 (18.9)	109 (53.0)	0 (0)	33 (16.0)
<i>Choked n</i>	5 (20.0)	8 (20.0)	16 (14.7)	-	2 (6.1)

¹⁻⁶Footnotes 1-6 outlined overleaf

Footnotes for Table 4.6

¹Data expressed as n (%).

²Adherence to a baby-led approach to infant feeding was defined as: not baby-led (always or mostly fed by an adult), partially baby-led (about half fed by an adult and half self-fed), baby-led (always or mostly self-fed), not yet started solids, or incomplete data.

³Represents the total number of infants in the study in each of the five categories of adherence at each study time point. The percentage is the percent of all infants *of that age* (e.g., percent of all 0 to <6 month olds) who were in that adherence category.

⁴Represents the total number of infants in each category of adherence who choked at least once at that time point. The percentage is the percent of infants of that *age and adherence category* (e.g., percent of 0 to <6 month olds who were not baby-led) who choked.

⁵2 of these participants had not been fed solids in the seven days prior to the questionnaire.

⁶1 participant had not been fed solids in the seven days prior to the questionnaire.

4.3 Gaggling

Table 4.7 shows that infants in the BLISS group were significantly more likely to gag at least once at 6 months of age, than infants in the Control group. The estimates provided by the two different data sources were broadly comparable, with BLISS infants being 17% (95% CI 5% - 31%) more likely to gag at least once at 6 months of age than infants in the Control group (questionnaire), with corresponding figures of 13% (95% CI 1% - 26%) for the calendar data. There were no other differences between the groups at any time-points, by either questionnaire or calendar.

Table 4.7 Number of infants in the Control and BLISS groups who gagged each month, by questionnaire and calendar ¹

<i>Age ²</i>	<i>Control</i>	<i>BLISS</i>	<i>RR (95% CI) ³</i>	<i>p ⁴</i>
<i>Gagged at least once, by questionnaire ⁵</i>				
0 to <6 months	51/85 (60.0%)	57/96 (59.4%)	0.99 (0.78, 1.26)	0.930
6 months	71/88 (80.7%)	89/94 (94.7%)	1.17 (1.05, 1.31)	0.006
7 months	63/83 (75.9%)	71/91 (78.0%)	1.03 (0.87, 1.21)	0.722
8 months	72/88 (81.8%)	78/95 (82.1%)	1.01 (0.88, 1.16)	0.855
11 months	38/81 (46.9%)	42/93 (45.2%)	1.04 (0.79, 1.37)	0.778
<i>Gagged at least once, by calendar</i>				
6 months	66/79 (83.5%)	80/85 (94.1%)	1.13 (1.01, 1.26)	0.034
8 months	66/73 (90.4%)	67/79 (84.8%)	0.94 (0.84, 1.06)	0.338

¹ Data expressed as number of participants who gagged/number of participants with data (%).

² Months refer to whole months, unless stated otherwise, so that '5 months' refers to 5.0 to 5.9 months of age.

³ Relative risk in BLISS participants compared to Control participants. Data were analysed using Poisson regression with robust standard errors, controlling for maternal education and parity (the stratification variables used at randomization).

⁴ P value is for relative risk in BLISS participants compared to Control participants, controlling for maternal education and parity (the stratification variables used at randomization).

⁵ Questionnaire data were collected retrospectively at the beginning of the next month. For example, the data reported here for age 6 months were collected in the 7 month questionnaire.

Table 4.8 describes the mean *number* of gagging events per infant at each time-point, by study group. At 6 months of age, infants in the BLISS group gagged significantly more often than infants in the Control group (RR 1.56, 95% CI 1.13 to 2.17), whereas at 8 months of age, BLISS infants gagged less frequently than Control infants (RR 0.60, 95% 0.42 to 0.87). There were no significant differences at the other time-points.

Table 4.8 Mean number of gagging events per infant, per month^{1, 2}

Age ³	Control ⁴	Min, max	BLISS ⁴	Min, max	RR (95% CI) ⁵	P value ⁶
0 to <6 months	7.8 (15.0)	0, 90	14.0 (35.1)	0, 270	1.81 (0.97, 3.38)	0.062
6 months	9.4 (11.3)	0, 60	14.7 (16.7)	0, 105	1.56 (1.13, 2.17)	0.008
7 months	7.5 (12.5)	0, 90	7.9 (10.3)	0, 60	1.05 (0.69, 1.61)	0.809
8 months	9.4 (15.1)	0, 90	5.6 (5.6)	0, 30	0.60 (0.42, 0.87)	0.006
11 months	7.5 (17.2)	0, 90	5.8 (11.5)	0, 60	0.79 (0.42, 1.48)	0.458

¹Data presented as mean (SD).

²Data collected by questionnaire

³Months refer to whole months, unless stated otherwise, so that '6 months' refers to 6.0 to 6.9 months of age. Questionnaire data were collected retrospectively at the beginning of the next month. For example, the data reported here for age 6 months were collected in the 7 month questionnaire.

⁴Refer to Table 2 for the number of participants with data in each group, at each age.

⁵Data were analysed using negative binomial regression. Results are presented as relative risk of gagging in BLISS participants compared to Control participants, controlling for maternal education and parity (stratification variables used at randomisation).

⁶P value compares the mean number of gagging events per month among BLISS participants with the mean number among Control participants, controlling for maternal education and parity (stratification variables used at randomisation).

4.4 Parental feeding practices

Table 4.9 indicates that the percentage of infants in the study who *always* had a parent or other adult sitting with them while they ate never exceeded 80.5% (Control group, 6 months of age) and was as low as 44% (Control group) at 11 months of age. At this time-point, participants in the BLISS group were almost twice as likely (97%; 95% CI 9%-256% more likely) to have a parent or other adult sitting with them while they ate, but there were no significant differences between groups at any other time-point.

Table 4.9 Proportion of infants who always had a parent or other adult sitting with them while they ate ^{1, 2}

Age (months)	Control	BLISS	Odds Ratio (95% CI) ³	P ⁴
6	70/87 (80.5%)	71/92 (77.2%)	0.79 (0.39, 1.63)	0.530
7	62/83 (74.7%)	65/91 (71.4%)	0.85 (0.44, 1.67)	0.646
8	58/87 (66.7%)	71/95 (74.7%)	1.46 (0.77, 2.77)	0.245
11	36/81 (44.4%)	60/93 (64.5%)	1.97 (1.09, 3.56)	0.025

¹n(%) of infants who always had a parent or other adult sitting with them while they ate

²Data were analysed using ordered logistic regression.

³Results are presented as odds ratios, which are an estimate of moving from the lower categories to the higher categories using the proportional odds model.

⁴p-value compares the likelihood of moving from the lower categories to the higher categories using the proportional odds model.

Table 4.10 demonstrates that no significant differences in eating locations between groups were observed at any time-point. More than 85% of participants in both groups sat in a highchair or similar seat on at least some of their eating occasions. An average of 42.8% of participants across the two groups sat “on someone’s knee” on at least some eating occasions at each time-point, and similarly, an average of 41.5% of participants across the two groups also sat in at least one other location for at least some meals. “Other” eating locations are described in Appendix M: these included both restrained and unrestrained sites, such as in carseats and prams, on the floor, on sofas and in various pieces of baby equipment, such as bouncers and exersaucers.

Table 4.10 Eating locations of Control and BLISS participants, by time-point¹

Age	Control	BLISS	p ^{2 3}
<i>6 months^{4 5}</i>			
n	87	94	
Highchair/chair attached to table	74 (85.1%)	82 (87.2%)	0.672
Someone's knee	40 (46.0%)	31 (33.0%)	0.074
Other ⁶	37 (42.5%)	37 (39.4%)	0.655
<i>7 months^{4 5}</i>			
n	83	91	
Highchair/chair attached to table	81 (97.5%)	85 (93.4%)	0.188
Someone's knee	42 (50.6%)	35 (38.5%)	0.107
Other ⁶	35 (42.2%)	34 (37.4%)	0.517
<i>8 months^{4 5}</i>			
n	87	95	
Highchair/chair attached to table	81 (93.1%)	89 (93.7%)	0.875
Someone's knee	44 (50.6%)	35 (36.8%)	0.062
Other ⁶	36 (41.4%)	41 (43.2%)	0.808
<i>11 months^{4 5}</i>			
n	81	93	
Highchair/chair attached to table	77 (95.1%)	89 (95.7%)	0.841
Someone's knee	33 (40.7%)	43 (46.2%)	0.466
Other ⁶	35 (43.2%)	40 (43.0%)	0.979

¹ Data are presented as n(%)² Data were analysed using a chi-square test.³ P-value compares the proportion of infants in each group who sat in each location to eat, at each time-point.⁴ Parents were able to choose as many options as applied to their infant, therefore percentage totals do not add to 100%.⁵ The questionnaires collected data retrospectively at the end of each month, i.e. the data reported here for age 6 months were collected in the 7 month questionnaire⁶ "Other" locations at each time-point included a range of restrained and unrestrained locations. A complete list is outlined in Appendix M.

4.5 Infant exposure to foods thought to pose a choking risk

Table 4.11 reports the number of infants who were offered foods which were thought to pose a choking risk at least once over one to three days of weighed diet recording at 7 months of age. Statistical comparisons for each individual food could not be made due to the small number of infants who had been offered each item. However, in the Control group, the most commonly offered foods which were thought to pose a choking risk were baby rusks, raw vegetables and raw apple, which were offered at least once to 19.2%, 12.8% and 11.5% of participants respectively. In comparison, the most commonly offered foods in the BLISS group were baby rusks, hard crackers, and sausages and similar products, which were offered at least once to 14.0%, 12.8%, and 10.5% of participants respectively. In total, 48.7% of participants in the Control group and 54.7% in the BLISS group were offered at least one food which was thought to pose a choking risk during the three days of diet recording. Overall, there was no statistically significant difference in the proportion of infants in each group who were offered at least one food thought to pose a choking risk over these three days (RR 1.12, 95% CI 0.79 – 1.59).

Table 4.11 Number of infants offered a food thought to pose a choking risk at least once during the 3-day weighed diet record at 7 months of age¹

Food thought to pose a choking risk ²	Control (n=78) ³	BLISS (n=86) ⁴	RR (95%CI) ⁵	p ⁶
Baby rusks	15 (19.2)	12 (14.0)	-	-
Raw vegetables	10 (12.8)	6 (7.0)	-	-
Raw apple	9 (11.5)	1 (1.2)	-	-
Sausages and similar products	2 (2.6)	9 (10.5)	-	-
Meat (not including sausages)	8 (10.3)	5 (5.8)	-	-
Hard crackers	6 (7.7)	11 (12.8)	-	-
Peas	6 (7.7)	7 (8.1)	-	-
Corn	5 (6.4)	5 (5.8)	-	-
Whole grapes	4 (5.1)	4 (4.7)	-	-
Dried fruit	2 (2.6)	2 (2.3)	-	-
Marshmallow	1 (1.3)	0 (0.0)	-	-
Popcorn	1 (1.3)	0 (0.0)	-	-
Whole cherries	1 (1.3)	0 (0.0)	-	-
Berries	0 (0.0)	1 (1.2)	-	-
Crisps	0 (0.0)	1 (1.2)	-	-
Corn chips	0 (0.0)	1 (1.2)	-	-
Seeds	0 (0.0)	1 (1.2)	-	-
Whole cherry tomatoes	0 (0.0)	1 (1.2)	-	-
Battered fish	0 (0.0)	0 (0.0)	-	-
Chewing gum	0 (0.0)	0 (0.0)	-	-
Small/hard/sticky candy	0 (0.0)	0 (0.0)	-	-
Raw pineapple	0 (0.0)	0 (0.0)	-	-
Whole nuts	0 (0.0)	0 (0.0)	-	-
Any food posing a choking risk	38 (48.7)	47 (54.7)	1.12 (0.79-1.59)	0.52

¹ Data presented as n (%).

² Described in the list of foods thought to pose a choking risk in Figure 3, and in detail in Appendix L.

³ Altogether, 225 days of diet recording were completed by the Control group (Day 1 was completed by 78 participants, Day 2 by 74, and Day 3 by 73).

⁴ Altogether, 246 days of diet recording were completed by the BLISS group (Day 1 was completed by 86 participants, Day 2 by 83, and Day 3 by 77).

⁵ Data were analysed using Poisson regression. Results are presented as relative risk of being offered a food posing a choking risk in BLISS participants compared to Control participants.

⁶ P value compares the number of participants being offered at least one food posing a choking risk during weighed diet recording among BLISS participants with the number among Control participants.

Table 4.12 presents similar data at 12 months of age. As with the data at 7 months, statistical comparisons for each individual food could not be made due to the small numbers. The most commonly offered foods thought to pose a choking risk at this age were hard crackers (47.8%), meat (36.2%) and whole grapes (31.9%) in the Control group and hard crackers (46.7%), peas (38.7%), and raw vegetables (36.0%) in the BLISS group. In total, virtually all children (97.1% Control, 92% Bliss) were offered at least one food which was thought to pose a choking risk during weighed diet recording (RR for difference between the groups 0.94, 95% CI 0.83-1.07).

Table 4.12 Number of infants offered a food thought to pose a choking risk at least once during the 3-day weighed diet record at 12 months of age¹

Food thought to pose a choking risk ²	Control (n=69) ³	BLISS (n=75) ⁴	RR (95% CI) ⁴	p ⁵
Hard crackers	33 (47.8)	35 (46.7)	-	-
Peas	18 (26.1)	29 (38.7)	-	-
Meat (not including sausages)	25 (36.2)	23 (30.7)	-	-
Raw vegetables	18 (26.1)	27 (36.0)	-	-
Whole grapes	22 (31.9)	20 (26.7)	-	-
Dried fruit	21 (30.4)	14 (18.7)	-	-
Raw apple	20 (29.0)	16 (21.3)	-	-
Sausages and similar products	18 (26.1)	21 (28.0)	-	-
Corn	18 (26.1)	17 (22.7)	-	-
Crisps	12 (17.4)	8 (10.7)	-	-
Baby rusks	6 (8.7)	3 (4.0)	-	-
Popcorn	5 (7.2)	0 (0.0)	-	-
Berries	3 (4.3)	3 (4.0)	-	-
Whole cherry tomatoes	3 (4.3)	3 (4.0)	-	-
Pineapple	2 (2.9)	2 (2.7)	-	-
Whole cherries	2 (2.9)	1 (1.3)	-	-
Small/hard/sticky candy	1 (1.4)	2 (2.7)	-	-
Marshmallow	1 (1.4)	1 (1.3)	-	-
Seeds	1 (1.4)	1 (1.3)	-	-
Whole nuts	1 (1.4)	1 (1.3)	-	-
Battered fish	0 (0.0)	4 (5.3)	-	-
Chewing gum	0 (0.0)	0 (0.0)	-	-
Corn chips	0 (0.0)	0 (0.0)	-	-
Any food posing a choking risk	67 (97.1)	69 (92.0)	0.94 (0.83-1.07)	0.36

¹ Data presented as n (%).

² Described in the list of foods thought to pose a choking risk in Figure 3, and in detail in Appendix L.

³ Altogether, 198 days of diet recording were completed by the Control group (Day 1 was completed by 69 participants, Day 2 by 64, and Day 3 by 65).

⁴ Altogether, 220 days of diet recording were completed by the BLISS group (Day 1 was completed by 75 participants, Day 2 by 73, and Day 3 by 72).

⁵ Data were analysed using Poisson regression. Results are presented as relative risk of being offered a food thought to pose a choking risk in BLISS participants compared to Control participants.

⁶ P value compares the number of participants being offered at least one food thought to pose a choking risk during weighed diet recording among BLISS participants with the number among Control participants.

4.6 Growth faltering

No growth faltering was observed in either study group at any time-point between 6 and 9 months of age.

4.7 Growth triggers

Table 4.13 describes the number of infants who met BLISS study growth triggers between 6 and 12 months of age. In total, 32 infants (16 Control, 16 BLISS) met at least one growth trigger. This included 5 infants (Infants 1040 and 0448 from the Control group, and Infants 0961, 1230 and 0930 from the BLISS group) who met more than one growth trigger. Three of the 5 infants (Infant 0448 from the Control group, and Infants 0961 and 1230 from the BLISS group) were referred to the study paediatrician for clinical assessment because their measurements and growth history indicated that they were potentially at risk of growth faltering.

The growth trigger which was most commonly met was 3 (no increase in an infant's weight for at least one successive measurement between 6 and 9 months of age) which was met by a total of 21 infants (11 Control, 10 BLISS). Of these 21 infants, 3 (2 Control, 1 BLISS) had no change in weight between two measurements, while 18 (9 Control, 9 BLISS) had lost weight. Of the 18 infants who lost weight, 7 (4 Control, 3 BLISS) lost between 10-49g, 10 (5 Control, 5 BLISS) lost between 50-99g, and 1 (BLISS) lost 200g. Notably, none of the 21 infants met Trigger 3 at more than one of the time-points between 6 and 9 months of age (i.e. all infants subsequently went on to gain weight before their next measurement). Brief case studies of the 3 infants who met Trigger 3, as well as at least one other growth trigger between 6-12 months, are described in Table 4.14. Brief case studies outlining the growth progression of all infants who met Trigger 3 only are outlined in Appendix N.

Table 4.13 Number of infants who met BLISS study growth triggers between 6 and 12 months of age ^{1 2}

	Age (months)	Control ^{8 9}	BLISS ^{10 11}
Growth Trigger 1 ³	6	2/86 (2.3%)	1/97 (1.0%)
Growth Trigger 2 ⁴	6	2/86 (2.3%)	3/97 (1.0%)
Growth Trigger 3 ⁵	6-7	3/83 (3.6%)	1/93 (1.1%)
	7-8 ⁶	2/80 (2.5%)	5/91 (5.5%)
	8-9	6/81 (1.2%)	4/91 (4.4%)
	6-8	0/77 (0.0%)	0/90 (0.0%)
	6-9	0/83 (0.0%)	0/94 (0.0%)
Growth Trigger 4 ⁶	6-7	0/83 (0.0%)	0/93 (0.0%)
	7-8	0/80 (0.0%)	0/91 (0.0%)
	8-9	0/81 (0.0%)	0/91 (0.0%)
	6-8	0/77 (0.0%)	0/90 (0.0%)
	6-9	0/83 (0.0%)	0/94 (0.0%)
	6-12	0/77 (0.0%)	2/92 (2.2%)
Growth Trigger 5 ⁷	6-12 ⁷	3/77 (3.9%)	4/92 (4.3%)

¹ n(%)

² Denominators vary according to the number of participants who provided data.

³ Weight-for-age z-score less than -2 at 6 months of age

⁴ BMI-for-age z-score less than -2 at 6 months of age

⁵ No increase in weight for at least one successive measurement between 6 and 9 months of age

⁶ Decrease in weight-for-age z-score of greater than 1 between 6 and 12 months of age

⁷ Decrease in BMI-for-age z-score of greater than 1 between 6 and 12 months of age

⁸ Two Control infants met more than one growth trigger. Infant 1040 had a weight z-score (trigger 1) and a BMI z-score (trigger 2) of less than -2 at 6 months of age. Infant 0448 had no weight change at 8-9 months of age (trigger 3), and a decrease in BMI z-score from 6-12 months of greater than -1 (trigger 5).

⁹ One infant (Infant 0448) was referred to the study paediatrician because they met a growth trigger at 12 months of age (trigger 5), and were unwell (growth trigger 3 was also met by Infant C at 8-9 months, but a referral was not required at that stage).

¹⁰ Three BLISS infants met more than one growth trigger. Infant 0961 had a weight z-score (trigger 1) and a BMI z-score (trigger 2) of less than -2 at 6 months of age. Infant 1230 had no weight change at 7-8 months of age (trigger 3), a decrease in weight z-score from 6-12 months of greater than -1 (trigger 4), and a decrease in BMI z-score from 6-12 months of greater than -1 (trigger 5). Infant 0930BH had no weight change at 8-9 months of age (trigger 3), and a decrease in BMI z-score from 6-12 months of greater than -1 (trigger 5).

¹¹ Two BLISS infants (Infant 0961 and Infant 1230) were referred to the study paediatrician. Infant 0961 met two growth triggers (trigger 1 and trigger 2), with both being of a level which concerned the study paediatrician (both z-scores were below -3). Infant 1230 was referred to the study paediatrician because they met a growth trigger (trigger 3), had been unwell and were noted to have gained very little weight between 6-8 months of age (growth triggers 4 and 5 were also met when Infant 1230 reached 12 months of age).

Table 4.14 provides a brief summary of the growth trajectory of each of the infants who met at least one of the BLISS study growth triggers 1, 2, 4 and 5 between 6 and 12 months of age. Information on growth trigger 3 is presented if that trigger was met in addition to at least one other growth trigger (information on children who met trigger 3 only is presented in Appendix N). The table demonstrates that although 14 infants met at least one of these triggers, only Infant 0448 (Control), Infant 0961 and Infant 1230 (both BLISS) needed to be referred to the study paediatrician for clinical assessment. It also shows that in all cases, growth parameters were observed to improve over time, indicating that any slowing in growth was transient in nature.

Table 4.14 Growth details of infants who met at least one of the growth triggers 1, 2, 4, 5 (and 3 if 3 was present in addition to another growth trigger)¹

ID Group	Age (months)	Trigger	Referral to paediatrician	Reason for meeting trigger	Paediatrician advice	Follow-up findings	End point (as advised by paediatrician)
1766 Control	6	1	×	Weight-for-age z-score: -2.02.	Follow standard study measurement schedule and advise of weight and weight-for-age z-score at 7 months.	At 7 months, weight was 5.97kg and weight-for-age z-score was -2.09. The paediatrician considered the z-score to be stable but asked for continued notification of this infant's weight after each standard study measurement between 8-12 months.	At 12 months of age, infant's weight-for-age z-score had improved to -1.81. Infant was considered to be thin but growing satisfactorily. No extra measurements were needed between 12-24 months.
1040 Control	6	1 2	×	Weight-for-age z-score: -2.17 BMI-for-age z-score: -2.97.	Follow standard study measurement schedule and advise of weight and weight-for-age z-score at 7 months.	Weight at 7 months was 6.79kg and weight-for-age z-score was -1.85.	Satisfactory improvement: no need to notify of further measurements unless concerns arise.
0961 BLISS	6	1 2	✓	Weight-for-age z-score: -3.28 BMI-for-age z-score: -4.37.	Both z-scores are below -3 which may indicate substantial growth faltering: please refer.	See case study (Section 4.8).	See case study (Section 4.8).
0263 Control	6	2	×	BMI-for-age z-score: -2.22.	Follow standard study measurement schedule and advise of weight and weight-for-age z-score at 7 months.	Weight at 7 months was 7.41kg and weight-for-age z-score was -1.03.	7 month weight is satisfactory: no need to notify of further measurements unless concerns arise.

Table 4.14 continued: Growth details of infants who met at least one of the growth triggers 1, 2, 4, 5 (and 3 if 3 was present in addition to another growth trigger)¹

ID Group	Age (months)	Trigger	Referral to paediatrician	Reason for meeting trigger	Paediatrician advice	Follow-up findings	End point (as advised by paediatrician)
1176 BLISS	6	2	x	BMI-for-age z-score: -2.61.	Follow standard study measurement schedule and advise of weight and weight for-age z-score at 7 months.	Weight at 7 months was 7.44kg and weight-for-age z-score was -1.01.	Satisfactory weight gain between 6-7 months: no need to notify of further measurements unless concerns arise.
1158 BLISS	6	2	x	BMI-for-age z-score: -3.28.	Follow standard study measurement schedule and advise of weight and weight-for-age z-score at 7 months of age.	Weight at 7 months was 6.13kg and weight-for-age z-score was -1.82. The paediatrician asked to be notified of the infant's standard study measurements between 8-12 months as he was concerned that this child may need to be referred on. At 12 months, BMI-for-age z-score had improved to -2.25kg. No referral was required but the paediatrician recommended one extra measure at 18 months of age.	Satisfactory weight gain between 12 and 18 months; return to standard study measurement schedule.
1230 BLISS	7-8	3	✓	Weight decreased by 30g	Weight history also shows gain of only 70g between 6-8 months: please refer.	See case study (Section 4.8)	See case study (Section 4.8)
	6-12	4	x	Weight-for-age z-score decreased by 1.02	Infant noted to be unwell prior to 12-month measurement. Given previous history, allow family to choose between a referral or an extra measurement at 15 months.	Family chose 15-month measurement over referral. Weight increased to 8.36kg at 15 months. Paediatrician requested one further extra measurement at 18 months (weight was 9.37kg), and then to be notified of 24 month weight (11.42kg).	Satisfactory weight gain between 12 to 15, then 15 to 18 and 18 to 24 months. No need for further follow-up after study completion.
	6-12	5	x	BMI-for-age z-score decreased by 1.42			

Table 4.14 continued: Growth details of infants who met at least one of the growth triggers 1, 2, 4, 5 (and 3 if 3 was present in addition to another growth trigger)¹

ID Group	Age (months)	Trigger	Referral to paediatrician	Reason for meeting trigger	Paediatrician advice	Follow-up findings	End point (as advised by paediatrician)
0448 Control	8-9	3	×	Weight decreased by 80g.	Extra measure at 10 months.	Weight increased by 360g between 9-10 months.	Satisfactory gain; return to standard study measurement schedule.
	6-12	5	✓	BMI-for-age z-score decreased by 1.00.	Weight history also shows overall gain of only 20g between 9 and 12 months (infant unwell between extra measure at 10 months, and 12 month measurement). Please refer.	See case study (Section 4.8)	See case study (Section 4.8)
0930 BLISS	8-9	3	×	Weight decreased by 80g.	Infant known to have been unwell. Extra measure at 10 months.	Weight increased by 100g between 9-10 months. Family referred (not via BLISS study) to paediatric services for investigation of child's respiratory concerns, so left under care of non-study paediatrician.	Weight gain is satisfactory and infant is being seen by another paediatrician who can also discuss any concerns. Return to standard study measurement schedule.
	6-12	5	×	BMI-for-age z-score decreased by 1.3.	Extra measure at 15 months; to be discussed with non-study paediatrician.	Weight increased by 590g between 12-15 months. BLISS paediatrician aware that other paediatrician believed this infant was thriving, but had some ongoing wheezing resulting from having had Rhinovirus.	As above.

Table 4.14 continued: Growth details of infants who met at least one of the growth triggers 1, 2, 4, 5 (and 3 if 3 was present in addition to another growth trigger)¹

ID Group	Age (months)	Trigger	Referral to paediatrician	Reason for meeting trigger	Paediatrician advice	Follow-up findings	End point (as advised by paediatrician)
1495 BLISS	6-12	4	×	Weight-for-age z-score decreased by 1.03.	Extra measure at 15 months.	Weight increased by 750g between 12-15 months and weight-for-age z score stabilised.	Satisfactory weight gain between 12-15 months; return to standard study measurement schedule.
1288 Control	6-12	5	×	BMI-for-age z-score decreased by 1.22.	Extra measure at 18 months.	Weight increased by 1495g between 12-18 months and BMI-for-age z-score also improved.	Satisfactory weight gain between 12-18 months; return to standard study measurement schedule.
1359 Control	6-12	5	×	BMI-for-age z-score decreased by 1.28.	Extra measure at 18 months.	Despite repeated attempts, this family could not be contacted for the extra measure at 18 months, or for the 24 month measurement. They were then withdrawn from the study due to being uncontactable.	-
0549 Control	6-12	5	×	BMI-for-age z-score decreased by 1.01.	Infant noted to be unwell prior to 12 month measurement. Extra measure at 13 months.	Weight increased by 370g between 12-13 months.	Satisfactory gain between 12-13 months; return to standard study measurement schedule.
1305 BLISS	6-12	5	×	BMI-for-age z-score decreased by 1.15.	Weight-for-age z-score is stable. BMI-for-age z-score may have been affected by error in length measurement. Extra measure at 18 months.	Weight increased by 1700g between 12-18 months, and increased again by 1260g between 18-24 months. Weight-for-age z-score improved from -1.13 at 12 months to -0.63 at 18 months.	Satisfactory increases between 12 and 18, and 18 and 24 months. No need for further follow-up after study completion.

¹ Infants who met Growth Trigger C, but no other triggers throughout the study, are described in Appendix N.

4.8 Case studies of the infants who were referred to the paediatrician

Table 4.15 presents a brief case study of each of the three infants (1 Control – Infant 0448 and 2 BLISS – Infants 0961 and 1230) for whom the study paediatrician requested a referral because they were potentially at risk of growth faltering. None of these three infants were found to be experiencing poor growth as a result of the method of complementary feeding being employed. Furthermore, none were found to have serious underlying health conditions. The growth parameters of Infant 0961 improved substantially between 6 and 12 months, while the BLISS approach was being followed. Of the remaining two infants, Infant 1230 (BLISS) appeared to be unsettled due to wind or reflux, which was likely to have been impacting on his food intake, and Infant 0448 (Control) had been unwell, and eating only limited amounts, prior to the measurement which preceded referral. The measurements of both infants improved over time.

Table 4.15 Case studies of infants who were referred to the BLISS study paediatrician

Infant	Group	Summary
1230	BLISS	This male infant met growth trigger 3 when he lost 30g between 7 and 8 months. The paediatrician also noted that he had only gained 70g between 6 and 8 months of age. A referral was requested and the family attended an outpatient appointment with the paediatrician when the infant was 9.5 months old. He was found to be growing and developing satisfactorily, but to be quite unsettled, possibly as a result of wind or reflux. Omeprazole was prescribed and an additional weight measurement at 11 months of age was requested. The infant gained 880g before this appointment, which the paediatrician considered to be satisfactory. However, the infant was unwell between the 11 and 12 month appointments, and met growth triggers 4 and 5 at 12 months. The paediatrician was notified and the family were offered the choice of a further referral, or an extra measurement at 15 months. They chose the extra measurement; the infant's weight then increased satisfactorily between 12-15, and then 15-18, months.

Table 4.15 continued: Case studies of infants who were referred to the paediatrician

Infant	Group	Summary
0448	Control	<p>This female infant first met growth trigger 1 at 8-9 months, when she lost 80g. She then gained 360g between 9 and 10 months, which was considered to be satisfactory by the paediatrician, but went on to meet growth Trigger 3 at 12 months. She had been unwell between 10 and 12 months, and the paediatrician noted from her growth history that her overall weight gain between 9-12 months was only 20g. A referral was therefore requested, but the family did not attend a scheduled outpatient appointment with the paediatrician so no clinical assessment was completed. When contacted by a BLISS research assistant, the family agreed to an extra measure at 15 months of age. The infant's weight increased by 1.035kg between 12-15 months, at which time the family reported that she was eating well and there were no other concerns. As a result, no further follow-up, other than the usual 24-month BLISS study measurement, was deemed necessary.</p>
0961	BLISS	<p>This male infant met growth triggers 4 and 5 at 6 months of age. Although these were cross-sectional measures and no growth history was available to the paediatrician, he was concerned that both figures were below -3 (weight-for-age z-score of -3.28 and BMI-for-age z-score of -4.37), and requested a referral. The family attended an outpatient appointment and the paediatrician noted that while the infant did have the visual appearance of a child with growth faltering, he appeared to be developing normally and the parents did not have any concerns. Biochemical indices were checked, and all were within normal ranges, although iron levels were at the lower end of normal. The paediatrician recommended that the infant be given extra feeds of an iron-fortified formula to help top up his iron levels, but otherwise felt that it was safe to proceed with the BLISS approach. Reassuringly, steady improvements were then observed in the infant's growth</p>

indices (weight-for-age z-scores were -3.28, -2.65, -1.56, -0.99 and 0.40 at 6, 7, 8, 9 and 12 months respectively, and BMI-for-age z-score improved from -4.37 at 6 months to 0.88 at 12 months). The paediatrician assessed the infant again when he was 14 months old, and at this stage neither he nor the infant's parents had any concerns. It was concluded that this infant had simply been ready for complementary foods by six months of age.

5. Discussion

5.1 Choking

5.1.1 Key findings

Episodes of choking and gagging were reported among infants in both groups at each time-point. There were no significant differences in the proportion of infants in each group who choked at least once at any time point, and the characteristics of the most serious choking events appeared similar between the two study groups. At 7 months of age, approximately half (52%) of all infants were offered a food thought to pose a choking risk during weighed diet recording; by 12 months, this had increased to nearly all (95%) infants across both groups. Gagging was significantly more common and more frequent among BLISS infants than Control infants at 6 months of age. However, BLISS infants gagged less frequently than Control infants at 8 months of age. Safe feeding practices were not always observed in either group; by 11 months of age, less than two-thirds of all infants always had an adult sitting with them while they ate. Furthermore, although most infants sat in secure locations (such as highchairs) on at least some eating occasions, many parents also reported that their infant sometimes ate in less safe locations (such as in a walker or carseat).

5.1.2 Comparison to existing literature

It is difficult to compare these findings with other literature, primarily because very little has investigated choking in relation to baby-led approaches to infant feeding. Furthermore, all existing data comes from one research group and each study was small^{11,13,37-38}. First, in a small content analysis study conducted by Cameron et al¹¹, 30% of mothers who identified themselves as having followed a BLW approach with their infant reported that the infant had choked one or more times. However, 30% only corresponded to 6 mothers, and the data was also potentially limited by recall bias because it was collected retrospectively. A larger subsequent study was undertaken by the same researchers¹³ using an online survey in 199 mothers who were following conventional feeding methods or BLW to varying degrees. This study reported that 32.6% of infants had choked at least once with no

significant differences between groups. The estimates from both surveys by Cameron et al appear consistent with the current finding that 35% of infants across both groups in the BLISS randomised controlled trial with complete questionnaire data between 6 and 8 months of age had choked at least once. In comparison, the rate of choking among participants in the BLISS pilot study was considerably lower, at only 13%. However, the pilot study was small (n=23) and of short duration (12 weeks)³⁸ when compared to both the 12-month BLISS intervention and the online survey, which asked whether infants had ever choked (notably, the mean age of the infants in the online survey was 8.6 months).

The only other study which appears to have examined choking according to different styles of complementary feeding investigated exposure to choking risk foods rather than choking itself. Morison et al³⁷ investigated whether infants who followed BLW (n=25) were more likely to be offered foods thought to pose a choking risk than infants following traditional spoon feeding methods (n=26). While no statistically significant difference was observed (OR 2.57, 95% CI 0.63 to 10.44)³⁷, the authors highlighted that the wide confidence interval included values which were consistent with a potential increase in the odds of BLW infants being offered foods thought to pose a choking risk so this possibility could not be ruled out. In total, 69% of the infants in Morison's study were offered foods which were thought to pose a choking risk at 7 months of age³⁷, compared to the 52% observed in the BLISS study at the same age. It is possible that the lower total percentage observed in the BLISS study is related to the advice about reducing the risk of choking which was provided to parents in the intervention group, or to all parents in the study being more conscious of the risk of choking due to the repeated collection of data about choking and gagging events. In any case, the findings of Morison et al and of the current project indicate that it is not uncommon for New Zealand infants to be offered foods which are thought to pose a choking risk.

5.1.3 Characteristics of choking events

From the data describing the characteristics of the 129 most serious choking events reported by parents in the BLISS study, it was clear that most events occurred when infants were feeding themselves (84.5%) and when foods of a 'whole' consistency were offered

(58%). This was initially concerning, as infant self-feeding and the offering of whole foods are hallmarks of baby-led approaches⁵⁻⁶. Furthermore, adherence to following a baby-led approach in the BLISS group, and to not following one in the Control group, was not complete; it was therefore possible that an association between baby-led approaches and choking was masked in the intention-to-treat analysis. However, when the data were described by adherence to a baby-led approach (i.e. according to behaviour rather than group) (Table 4.6), it was apparent that infants who did not feed themselves at all were just as likely to choke as infants who fed themselves partly or completely.

Overall, infants resolved approximately half (51%) of the most serious episodes of choking themselves, with parents resolving a further 37% of episodes. The percentage of parents resolving events appeared to be higher in the BLISS group than in the Control group at all study time-points except 12 months. This was particularly noticeable at 7 months, when parents resolved 63.6% of choking events in the BLISS group, compared to only 14.3% of events in the Control group. While this could be considered an indication that the choking episodes in the BLISS group were of a more serious nature than those in the Control group, it is also possible that parents in the BLISS group were more aware of the risk of choking because they had been given specific advice to minimise the risk, and were therefore more likely to intervene earlier when presented with an episode of choking.

It is important not to overlook the choking episodes which had different characteristics from those described above. Both of the choking events which were defined as serious adverse events were the result of infants choking on milk. While milk is an essential food for this age group and would not usually be considered to pose a choking risk¹, it is notable that milk was responsible for 36.3% of choking episodes in children aged <1 year in work from the USA⁵¹. Overall, the majority (77%) of the foods and liquids which were choked on by infants in the BLISS study were not items from the list of foods thought to pose a choking risk to infants (Figure 3 and Appendix L). Furthermore, episodes of choking were not limited to the beginning of the complementary feeding period, but were observed in both groups at all time-points, including between 0 and 6 months (when theoretically solid foods have not yet been introduced) and at 12 months of age (by which time infants would generally be

expected to be reasonably experienced feeders). It is therefore apparent that infants aged 0 to 12 months can, and do, choke on food and drinks of a variety of consistencies, despite the perceived 'safety' or otherwise of individual food items, and the feeding approach being employed by parents and caregivers. Some infants may also be more prone to choking than others. While frequency data showed that most infants who choked at any given time-point did so only once or twice, there were three infants (2 Control, 1 BLISS) who choked 6 or more times within a one-month period. However, not all of these cases appeared to be directly related to food, with one BLISS group mother reporting at the 5.5 month visit that her infant appeared to gag and choke on her own saliva.

5.1.4 Important lessons from a choking event in the BLISS group

The two choking episodes (1 Control, 1 BLISS) which were defined as serious adverse events were caused by milk feeds and thus were not related to the method of complementary feeding. However, in the third most serious event, an 8-month old female infant in the BLISS group choked on a piece of steamed apple which had been placed directly in her mouth by a parent. This action contradicted BLISS advice that only the infant should put food in their mouth (Figure 1). The infant's mother had previously raised concerns about her development. Following discussion with one of the study paediatricians, and with the support of the BLISS team, the family decided to proceed with a mixed approach to complementary feeding, which consisted of some conventional spoon-feeding combined with some infant self-feeding. Such approaches are endorsed in BLW, provided that parents have first sought advice from health professionals^{5,10}. Following the choking incident, the parents admitted that they knew that food should not have been placed in the infant's mouth for her. That they still did so may be an indication that it can be frustrating for parents and caregivers to watch infants struggle with self-feeding, potentially resulting in unsafe attempts to "help". Concern about an infant's development may not be the only situation in which parents wish to help with feeding; for example, if a child is unwell or very tired, or the family is in a hurry, parents may also choose to intervene¹¹. However, if baby-led approaches to infant feeding are to be recommended at a population level, it needs to be clear that parents must never place whole foods in their infants' mouths. Emphasis should be placed on the fact that if there are occasions when baby-led approaches cannot

be implemented patiently and safely, conventional feeding practices should be employed instead.

5.1.5 Offering of foods thought to pose a choking risk

Although the majority of the foods that infants in the BLISS study choked on were not items from the list of foods thought to pose a choking risk, it was still concerning to see such high percentages of infants in both study groups being offered items from the list. There are several possible explanations for this. First, the list of foods thought to pose a choking risk may have been too extensive, resulting in an overestimation of the number of infants who were offered foods which pose a choking risk. This possibility is described in more detail in Section 5.1.9. However, there are a number of other possible explanations. In a survey of 492 American parents of children aged <4 years, Nichols et al found that parents were more aware of non-food choking hazards (such as coins and small toys) than of foods which were thought to pose a choking risk¹²². The parents who were aware of foods which were thought to pose a choking risk were less likely to offer them to their children, leading to the conclusion that more parental education was needed¹²². By comparison, in New Zealand very detailed advice about reducing the risk of choking in infants is available¹ (Appendix A). However, it is possible that this information does not consistently reach parents, or is overshadowed by other important topics, such as breastfeeding, vaccinations and safe sleeping practices. It is also possible that the information provided is not easily applied or that the detail supplied is overwhelming and difficult to remember. More general guidelines, such as those provided in the BLISS intervention (for example “choose foods which are soft enough to mash on the roof of your mouth”) may be easier to remember and apply, although it is notable that parents in the BLISS group of the current study appeared just as likely to offer their infants foods which were thought to pose a choking risk, as parents in the Control group. Further possible explanations for the offering of foods which are thought to pose a choking risk include that parents may be influenced by factors other than choking risk (such as ease of food preparation, cost, and personal preference) when selecting food for their infants¹²², or that they may not want to limit foods which are ‘healthy’ (such as raw vegetables and raw apple) in their infant’s diet, or in their own diet if they are sharing meals, even if they recognise that some of these foods pose a choking

hazard. The latter suggests a need to continue including advice on how to safely modify foods which are thought to pose a choking risk within infant feeding guidelines; however, it may also be beneficial to consider whether there are ways of presenting this information more concisely in the future.

5.1.6 Parental feeding practices

Parental feeding practices with a focus on safety (such as seating infants in a secure place and supervising them closely while they eat) both reduce the risk of choking and ensure that any unavoidable events which do arise can be promptly identified and managed^{1,39}. It was therefore particularly concerning to see a lack of consistently safe feeding practices among both groups in the BLISS study. Other studies have also observed a lack of reliably safe feeding practices: Nichols et al found that only 76% of parents with children aged <4 years always supervised meals, and only 62% of parents knew CPR¹²², while Higuchi et al found that 18.1% of mothers did not know that they should not allow a child to walk or laugh while eating¹³¹.

Supervision

Parents in the BLISS study were not asked why they did not sit with their child each time they ate. However, it is possible that they were preparing food for themselves or other family members, attending to other children, or doing other activities while the infant ate. It is also possible that had the question been worded “do you, or another adult, closely supervise your infant on each eating occasion?” different findings would have resulted, because parents may not feel a need to physically sit with and watch their child while supervising. However, doing so would usually ensure a clear view of the infant’s face, which is essential in the prompt identification and management of choking episodes, especially those which are silent.

Eating locations

Although many infants sat in secure locations (such as highchairs) on at least some eating occasions, less secure locations (such as on a parent’s knee) were also common. This is a concern because an infant who is not in a secure location may not be able to maintain an

upright position, or may become more focused on other activities (such as playing or moving) than on eating. Furthermore, non-secure locations do not always provide the parent or caregiver with a clear view of the infant's face (especially if the infant is seated on their knee facing in a different direction, or is in a moveable piece of equipment such as an exersaucer or walker). Other locations, such as carseats, may be considered by some to be secure, but are inappropriate for other reasons – for example, parents in a moving car are unlikely to be constantly monitoring the infant's face (particularly if the carseat is rear-facing) and therefore may not be immediately aware of, or able to respond to, a choking event. Although the current NZ MOH guidelines do include comprehensive advice about safe feeding practices¹, it is possible that more emphasis in this area is required. The BLISS study finding that the foods responsible for the majority of most serious choking episodes were not items from the list of foods thought to pose a choking risk supports this suggestion, because if infants are going to choke even when appropriate foods are provided, then parents must constantly supervise them while they eat so that they can identify and manage choking events as they occur.

5.1.7 Gagging

The findings of the randomised controlled trial support Rapley's suggestion that gagging is common at the beginning of BLW, but becomes less frequent as time goes on^{5,10}. This may be due to a combination of factors. First, it would be expected that infants following baby-led approaches would become more skilled self-feeders (who are presumably less prone to gagging) between 6 and 8 months of age, and second, the gag reflex is known to move further back on the tongue during this time¹⁴, making gagging altogether less likely. It was notable that while the rates of gagging in the BLISS group decreased considerably between 6-11 months of age, the rates in the Control group remained reasonably consistent. This supports Rapley's suggestion that infants who follow baby-led approaches from the beginning of the complementary feeding period learn how to avoid gagging more quickly than infants who are not allowed to experiment with whole foods until later in infancy⁵.

5.1.8 Strengths

The BLISS approach was a version of BLW which included modifications to reduce the risk of food-related choking in infants⁹. A speech and language therapist with experience in the management of paediatric choking provided input into the development of the intervention messages about reducing the risk of food-related choking, and checked all of the study resources to ensure that none of the foods encouraged in the intervention were items which were thought to pose a choking risk to infants. The intervention messages were designed to be clear while also being concise and easy to remember; for example, rather than listing numerous 'hard foods' to avoid in Figure 2, general advice to avoid 'foods that you can't mash on the roof of your mouth with your tongue' was given. Furthermore, all of the resources were pilot-tested prior to the beginning of the BLISS randomised controlled trial.

In total, a large volume of data which provided information about both the frequency and characteristics of actual choking events, as well as infant exposure to foods thought to pose a choking risk and parental feeding practices, were collected and have been reported in this thesis. Two different methods of data collection (questionnaires and calendars) were used to assess the frequency of choking and gagging among infants in the BLISS study, and to check whether retrospective parental recall of events differed from events reported in 'real-time'. Reassuringly, the two methods gave similar results, as displayed in Tables 4.2 (choking) and 4.7 (gagging).

5.1.9 Limitations

Some of the data on food-related choking in this thesis could only be presented descriptively. This was because the BLISS study was powered primarily to detect group differences in infant BMI⁹, rather than in rates of choking. At each time point, only a small number of choking events were described, so it was not possible to determine whether the characteristics of these events differed by study group. Similarly, it was not possible to test whether infants in the BLISS group were more likely to be offered individual foods thought to pose a choking risk during their days of weighed diet recording at 7 and 12 months of age. A considerably larger sample size would be required to detect group differences in

these areas, and unfortunately this was not financially or practically feasible in the BLISS study. However, the descriptive findings appear similar between groups, and it therefore seems unlikely that group differences would have been observed even if the sample size had been larger.

The characteristics of each of the 129 most serious choking episodes were retrospectively reported by parents in the study questionnaires. While considerable efforts were made to ensure that parents in the BLISS study understood the differences between choking and gagging, it is still possible that some misclassification occurred. As a cross-check, the Candidate examined the data on choking symptoms to see how many events included at least one indication of airway compromise ('coughed', 'gasp', 'went silent'). The descriptions of 117 (92%) of the 127 episodes which were directly observed by a parent included at least one of these three symptoms, indicating that the overall rate of misclassification was low.

The phrase 'most serious choking event' was used in the questionnaires to ensure that the parent described the most severe choking episode for the relevant time period. However, for two reasons, it is likely that many of these events would not be considered serious from a clinical viewpoint. First, many infants had only one choking event for the relevant time period; no matter how minor these single events were, they were described as the 'most serious' for that time-point. Second, the infant alone resolved the choking episode in 51% of events, and only three cases (two of which involved milk feeds rather than solid foods) required the involvement of health professionals or hospital services.

The high proportions of infants identified as having been offered foods thought to pose a choking risk was influenced by the comprehensiveness of the food list (Figure 3 and Appendix L). The list was developed by comparing existing lists which varied in content and in degree of detail, and expert input was sought from an experienced speech and language therapist to assist with final decision making. The reasons for the inclusion and exclusion of specific foods are outlined in Appendix L, and therefore the list is a transparent tool. However, some decisions were difficult, especially as the speech and language therapist

advised that choking risk exists on a 'spectrum', with some foods sitting at the 'high risk' end, while others belong at the opposite 'low risk' end. This spectrum of risk could even exist within groups of foods, such as raw vegetables and crisps. A round piece of hard raw carrot, for example, poses a much greater choking risk than a soft piece of cucumber served in a stick shape. A traditional potato crisp is much harder than a vegetable crisp, and is more likely to be broken into small hard pieces in the mouth, whereas most vegetable crisps will dissolve and therefore pose a lesser risk. As all items across the 'spectrum of risk' were included in this work for consistency, it is possible that an overestimation of the number of infants who were offered foods thought to pose a choking risk resulted.

Despite the comprehensive information in the WDRs, it was sometimes difficult to ascertain whether certain foods had been served in a manner which posed a choking risk. This was best demonstrated by various types of meat which had been served 'diced'. The NZ MOH suggests that diced meat should be chopped to the size of a child's fingernail or smaller to reduce the associated choking risk; however, most WDRs did not include information about the dimensions of the diced pieces. Therefore, in a cautionary approach, all diced meat was generally considered to pose a choking risk. While it is possible that this resulted in an over-estimation of the number of infants who were offered foods thought to pose a choking risk during weighed diet recording, overall low numbers of infants were served meat which was considered to pose a choking risk (as outlined in tables 4.11 and 4.12) and therefore it is unlikely that this had much impact on the overall risk of infants being offered foods thought to pose a choking risk.

5.2 Growth faltering

5.2.1 Key findings

No infant in either study group met the BLISS study criterion for growth faltering (a decrease in weight-for-age z-score of greater than 1.34 between 6 and 9 months of age). However, 32 infants (16 Control, 16 BLISS) met at least one of the five BLISS study growth triggers at one or more time-points between 6 and 12 months of age. Five of the 32 infants (2 Control, 3 BLISS) met more than one growth trigger, but only 3 (1 Control, 2 BLISS) were subsequently referred to the paediatrician because of concern that they were potentially at risk of growth faltering. Reassuringly, none met the criterion for growth faltering, and the growth indices of all three infants were observed to improve over time. While statistical tests were not possible due to the small number of events, these descriptive findings do not suggest that infants who followed the BLISS approach to complementary feeding were at greater risk of growth faltering than infants in the Control group.

5.2.2 Comparison to existing literature

As with the choking findings presented in this thesis, it is difficult to compare the BLISS findings on growth faltering with other work, first because the BLISS approach was distinct in that it included modifications to reduce the risk of growth faltering in infants. Second, there are very few data on the rates of growth faltering in infants during the complementary feeding period. Although no New Zealand data are available, a recent UK study reported that when growth faltering is defined as the downwards crossing of two centile lines on the WHO growth charts (which was also the criterion used in the BLISS study), rates of growth faltering are very low ($\leq 0.5\%$), especially after the first four months of life⁶⁷. This is consistent with the finding that no infants in the BLISS study experienced growth faltering.

To date, no longitudinal studies other than the BLISS randomised controlled trial have investigated whether the prevalence of growth faltering among infants following baby-led approaches to complementary feeding is greater than it is among the general population, but a small amount of cross-sectional work investigating rates of 'underweight' among

infants following varying methods of complementary feeding does exist. Townsend and Pitchford compared the weights of infants who were spoon-fed (n=37) with those of infants who had followed BLW (n=37) and found a greater frequency of underweight (n=3 (4.8%) compared to 0 (0.0%)) in the BLW group³⁵. However, it is important to note that only infants in the spoon-fed group were weighed using standardised procedures, while the weights of infants in the BLW group were reported by parents. Parent-reporting of infant weights is sometimes inaccurate¹¹³ and therefore it is impossible to exclude the possibility that a different percentage of infants would have been identified if standardised weighing had been undertaken by Townsend and Pitchford, who used the WHO criterion (weight-for-age z-score of below -2)⁶¹ to define underweight. The same criterion was used in growth trigger 1 in the BLISS study (where it was met by 2 (2.3%) Control infants, and 1 (1.0%) BLISS infant) but the ages at which the criterion was applied were vastly different. The mean age of the infants who were tested by Townsend and Pitchford was 32.12 months³⁵, while in the BLISS study, growth trigger 1 was only applied at 6 months of age. This difference in age at testing is particularly important because participants in the BLISS intervention were encouraged to exclusively breastfeed until 6 months, so the rate of 'underweight' in the BLISS study at 6 months of age was theoretically unrelated to the method of complementary feeding, whereas the infants tested in Townsend and Pitchford's study had actually moved beyond the complementary feeding period (defined by the WHO as the period between 6 and 24 months of age) when they were tested. Therefore, neither growth trigger 1 in the BLISS study, nor the percentage of underweight infants reported by Townsend and Pitchford, reflect longitudinal infant growth during the early days of complementary feeding, when growth faltering might be expected to be more common among infants following a baby-led approach. Instead, they provide a cross-sectional 'snapshot' of the proportion of infants who had a weight-for-age z-score of below -2, and could therefore be described as underweight, at the time of testing.

Brown and Lee also included a measure of 'underweight' in their study of 298 infants following either BLW (n=163) or standard weaning (SW, n=135)²⁷. More infants in the BLW group (5.4%) than in the SW group (2.5%) were found to be underweight. However, 'underweight' was defined using a different criterion (infant weight <5th percentile for infant

age and sex according to the WHO-CGS) and again the infants in the study were older (mean age 21.46 months, range 18-24 months) than those in the BLISS study. Furthermore, not only were the infant weights in that study parent-reported, but 10.1% (n=30) of parents were unable to provide a current weight for their infant²⁷, perhaps adding further strength to the argument that parents may find it difficult to report accurate infant weights¹¹³.

In summary, the small amount of literature which is available for comparison with the results of the BLISS study does not provide an insight into the risk of growth faltering in the early days of complementary feeding. However, the BLISS study results support suggestions that the overall rate of growth faltering in infants more than four months old is very low ($\leq 0.5\%$)⁶⁷, and that is likely to be regardless of the method of complementary feeding being used.

5.2.3 Concurrency between BLISS study growth triggers

It is well known that different criteria for growth faltering will identify different infants⁶⁴, and therefore it is not surprising that the five growth triggers used in the BLISS study did not routinely identify the same infants at the same time-point. For example, at 6 months of age, a total of 6 infants were identified by growth triggers 1 or 2; however, only 2/6 infants met both triggers at this time-point. Furthermore, while 21 infants met growth trigger 3 at a time-point between 6 and 9 months of age, none of the 21 also met growth trigger 4 at the relevant time-point. However, it is important to recognise that the rationale behind using five different growth triggers in the BLISS study was to ensure that all infants who were potentially at risk of growth faltering were identified (and if necessary, assessed by the study paediatrician) as soon as possible. This was essential because of the concern about potential growth faltering in this population^{6,11}, and was deemed to be more important than demonstrating a good degree of concurrence between growth triggers.

5.2.4 Time period between measurements

When considering infant growth trajectories, the time period between measurements is an important consideration⁸³. There are disadvantages both to measurements which are taken too often^{109,110}, and those that are not taken often enough⁸³. In the BLISS study, infants

were weighed monthly between 6-9 months of age. This is more often than is usually clinically recommended; in the UK it is suggested that infants are weighed two-monthly between 6 and 12 months of age¹¹⁰, while the Well Child programme in New Zealand advocates weighing infants only at routine visits¹⁰⁸, which typically means one weight between 5 and 7 months, and another at 9 to 12 months¹¹¹. However, in other research settings, such as the MGRS, infants have been weighed monthly between 2-12 months of age⁸⁵. Such frequent measurements were thought to be appropriate in the BLISS study because growth faltering at the beginning of the complementary feeding period (when theoretically infants following baby-led approaches may ingest fewer calories than infants following more conventional feeding practices) had been recognised as a possible adverse event, which would need to be identified as soon as possible. However, in hindsight, it may have been adequate to have weighed the BLISS study infants once every two months. The rate at which growth trigger 3 identified infants in the BLISS study supports this suggestion. Overall, 21 infants were identified by this trigger at a time-point between 6-9 months of age. 18 of these infants had lost a small amount of weight, while the remaining 3 had maintained the same weight. It is possible that the use of different scales may have accounted for the lack of gain in two of these three participants, who had moved out of the district between measurements and who were weighed by Well Child providers in their new areas. The amount of weight actually lost by the 18 infants was small, with only one infant losing more than 100g. Furthermore, the amount of weight lost never equated to a decrease in weight-for-age z-score of >-1 between measurements (growth trigger 4), providing further evidence that the magnitude of weight loss was small and possibly of limited clinical importance. In some cases, the weight loss or lack of weight gain could be explained by an illness having affected the infant's food intake. In other cases, the parent was surprised by the lack of weight gain and could not offer an explanation; this may simply demonstrate that infant growth varies over time and may happen in 'spurts' rather than as a continuous increase¹⁰⁰. Reassuringly, each of the 21 infants went on to gain weight before their next measurement, indicating that the lack of weight gain the previous month had indeed been transient. It seems likely that if the infants in the BLISS study had been weighed two-monthly, very few, if any, would have met a criterion of 'no weight gain between successive measures', because the longer time-frame would be less likely to identify infants

experiencing short-term fluctuations in growth. Two-monthly weight measurements might therefore be appropriate in future research.

5.2.5 Paediatrician referrals

Although three infants were referred to the study paediatrician, none of them were found to be at risk of growth faltering due to the method of infant feeding being employed. The first of the two infants from the BLISS group was referred on the basis of very low weight-for-age (-3.28) and BMI-for-age (-4.37) z-scores at 6 months of age, before the complementary feeding period had officially begun. This infant's z-scores actually consistently improved while the BLISS approach was being followed, with both scores being >0 when the paediatrician conducted a further review at 14 months of age. It seems feasible that this infant was experiencing undernutrition caused by inadequate caloric intake⁷² prior to six months of age, which was resolved by nutritional management⁷⁴⁻⁷⁵ in the form of increased formula feeding and use of the BLISS approach to complementary feeding. The other two infants had both been unwell before the measurement which prompted the referral; in one case the (BLISS) infant was prescribed Omeprazole to reduce ongoing problems with wind, and in the other the (Control) child did not have a clinical assessment by the paediatrician as the family did not attend their scheduled outpatient appointment. The growth trajectories of both infants improved over the second year of life.

5.2.6 Strengths

As with choking, all parents in the BLISS intervention were provided with advice and resources to minimise the risk of growth faltering in their infants. Each of the resources had been pre-tested in the BLISS pilot study, which did not find any statistically significant difference between the amount of energy offered from complementary foods to infants in the BLISS and BLW groups.

A detailed protocol describing how anthropometric measurements were to be collected was developed by the BLISS study supervisory team (Appendix K). All of the blinded research assistants who were collecting anthropometric measurements were trained by the same

researcher, and their practices were observed by one of the study co-investigators on at least two occasions to ensure that the measurement protocol was being followed correctly. Once measurements were collected, they were compared to the WHO-CGS, which is a growth standard designed to provide a measure of how healthy children should grow⁸⁵. Although only one criterion was used to define growth faltering, infant growth was also compared with five “growth triggers” during the study, in order to ensure that all infants who were potentially at risk of growth faltering were identified as early as possible, so that expert intervention could be put in place if it was required. The study paediatrician was notified each time an infant met a growth trigger, and was provided with all of the infant’s measurements and health background so that a clinical judgement could be made and any problems identified promptly and expertly.

5.2.7 Limitations

The BLISS study was powered to detect differences in infant BMI, which was the main study outcome⁹; the resulting study numbers only allowed for the data on growth faltering to be examined descriptively. Recent estimates from the UK suggest that only 0.5% of children will display growth faltering (when it is defined as the downwards crossing of two centile lines on the WHO growth charts) after the first four months of life⁶⁷. When the prevalence of a condition is low, large sample sizes are required to identify individuals with the condition¹³² and then to detect group differences. The BLISS study would have required over one thousand participants to detect group differences in growth faltering, and unfortunately such a large sample was not financially or practically possible. However, given the lack of differences apparent in the descriptive findings, it seems unlikely that a larger study would have identified statistically significant group differences.

Despite the detailed measurement protocol and consistent staff training, some degree of measurement error would be expected to have affected the study results. In particular, the inaccuracy of length measurements among infants is well documented⁶⁹⁻¹⁰⁶, and may have impacted on the BMI-for-age z-scores of some infants at 6 or 12 months of age. To counteract this, duplicate (and if necessary, triplicate) weight and length measurements

were taken at each relevant time point, as per the protocol in Appendix K, and this inaccuracy would have applied equally to both groups.

5.3 Strengths of the BLISS study

The most obvious strength of the BLISS study was its robust randomised controlled trial design. Parents who follow BLW have different demographic, psychological and parenting characteristics to parents who follow conventional infant feeding practices^{9,13,30}, and other unknown confounders also have the potential to influence study findings. The only way to control for this is to randomly allocate families to either the control or intervention group in a randomised controlled trial. The BLISS study was the first research into baby-led approaches to complementary feeding to do this.

A further strength of the study was the high degree of adherence to the intervention. For example, at 7 months of age, 73% of infants in the BLISS group had followed a baby-led approach to infant feeding for the past week, suggesting that the BLISS approach was feasible for most families. Furthermore, the overall participant retention rate in the study was high, with 178 families (86%) remaining in the study when their infants reached 12 months of age. No families had withdrawn as a result of adverse choking or growth faltering events.

The intervention messages and related resources were developed and pilot tested in advance of the randomised controlled trial³⁸, and the intervention itself was delivered by an experienced lactation consultant and trained research staff, under the supervision of nutrition researchers and the BLISS multidisciplinary team of health professionals (paediatricians, speech language therapists and dietitians). Detailed protocols were developed for all standard operating procedures to ensure that consistent procedures were followed by all staff, and the study co-investigators also observed the practice of each research staff member at least twice during the study period to ensure that the protocols were being followed correctly. All research assistants who were involved in collecting outcome measurements were blinded to study groups throughout the intervention period.

5.4 Limitations of the BLISS study

Although the overall adherence rates in the BLISS study were satisfactory, complete adherence was not achieved in either the intervention or the Control group during the study. For example, at 7 months of age, 19% of participants in the Control group were found to be adherent to a baby-led approach, rather than to conventional complementary feeding practices. During the course of the study, it became apparent that some families in the Control group wished to follow baby-led approaches with their infants; similarly, a small number of families in the intervention group found the BLISS approach difficult and decided to follow more conventional feeding practices. Because of this, the data about the number of choking events per time point in this thesis was described by adherence (Table 4.6) as well as by study group (Table 4.4). Reassuringly, this analysis suggested that the results were not confounded by the degree of adherence to the intervention, although further analyses would need to be undertaken to confirm that there were no impacts in other areas.

It is possible that there was some crossover of intervention information between groups because Dunedin is a small city and some study participants were clearly known to each other, possibly through ante-natal classes or other infant-related activities. Although participants in the BLISS group were reminded not to share their resources and information at each intervention visit, there is no way of knowing whether they followed these instructions.

A further limitation is that it is difficult to determine the extent to which the findings of the BLISS study can be generalised to the New Zealand population as a whole. Overall, our sample was highly educated (49% of mothers had a university degree, compared to 28% of the general New Zealand population¹²⁸) and somewhat socio-economically advantaged (21% of families scored 8-10 on the NZDep13, compared to an expected 30%¹¹⁷), with 74% of mothers employed in a full or part-time capacity in late pregnancy. Furthermore, mothers in the BLISS sample were less ethnically diverse (82% New Zealand European, 12% Māori or Pacific, 6.3% Asian) than adults in the general New Zealand population (75% New Zealand European, 23.4% Māori or Pacific, 12.2% Asian). This was not surprising given that the BLISS sample was drawn from the Otago region, which is known to have more New Zealand

European, and fewer Māori, Pacific and Asian people, than the general New Zealand population¹³⁰. However, interestingly, infants in the BLISS sample were considerably more ethnically diverse (70% New Zealand European, 22% Māori or Pacific, 8% Asian) than their mothers, which compares reasonably well with national figures. In the BLISS study baseline questionnaire, mothers were asked about their own ethnicity, and that of the infant's father. The ethnicity of each infant was then determined using a prioritisation system recommended by Statistics New Zealand¹¹⁶. A limitation of this process was that the fathers of the BLISS infants were never personally asked about their ethnicity; it is possible that if they had been asked, some would have given different responses to those provided by the mothers. Furthermore, the use of the Statistics New Zealand prioritisation system means that each BLISS infant was allocated to only one ethnic group¹¹⁶. In comparison, in other data collections, such as the New Zealand census, individuals are able to choose as many ethnicities as they wish, and those who report more than one ethnic group will be counted in each applicable group¹³³. As a result of these limitations, the BLISS data on infant ethnicity should be treated with caution. Overall, it is not possible to exclude the possibility that if the BLISS study was replicated in different sample, either within New Zealand or internationally, different results would be obtained. However, to counteract this limitation, considerable efforts were made to recruit a diverse sample by inviting all Dunedin women (both those who were booked to give birth at Queen Mary Maternity, and those who were planning home births) to participate in the BLISS study.

5.5 Application of findings

The findings presented in this thesis are reassuring because they suggest that infants who follow the BLISS approach to complementary feeding are not likely to have an increased risk of food-related choking or growth faltering in the first year of life. However, it is important to remember that the BLISS approach differed from other baby-led approaches to infant feeding because it included specific modifications to reduce the risk of both food-related choking and growth faltering. Therefore, the BLISS results are not directly generalizable to infants and families who are following BLW or other baby-led approaches to infant feeding in the wider community; it is still possible that the risk of food-related choking and growth

faltering among those infants is greater than the risk among infants following conventional feeding practices.

These results are likely to be of interest to parents, health professionals and policy makers alike, and should be useful for policy makers when the NZ MOH infant feeding guidelines are revised. Such revision would need to take a number of factors into consideration. Firstly, it is known that some families are not interested in baby-led approaches¹³. Secondly, the aim of the study was not to determine whether baby-led approaches should replace conventional infant feeding methods, but rather to investigate whether they could safely be recommended as an alternative approach for interested families. Therefore, if baby-led approaches were to be recommended on a population level, revised infant feeding guidelines would need to incorporate relevant advice while also retaining existing messages about conventional methods. Furthermore, the BLISS study investigated a number of other outcomes that would need to be considered before policy changes could be made. These include whether there was any difference in infant BMI, iron and zinc status, or overall diet quality between the BLISS and Control groups, and whether the BLISS approach was realistic for families and acceptable to parents in terms of cost, mess and convenience. In particular, the BLISS results about growth faltering would need to be considered in conjunction with the findings about infant BMI at 12 months of age. Families in the intervention group were encouraged to offer their infants at least one high-energy food at each meal to reduce the risk of growth faltering. It is possible that this could have had the unintended effect of increasing infant BMI beyond desirable levels during the complementary feeding period; if so, this would need to be addressed before population recommendations were made.

If infant feeding guidelines were revised to include messages about baby-led approaches to complementary feeding, economical strategies would be needed to ensure that relevant safety advice about minimising the risk of food-related choking was readily available to parents and caregivers. The Candidate believes that it would be appropriate to train Well Child providers in the safety messages from the BLISS study, and to encourage all providers to routinely enquire about complementary feeding at both the infants' 3-4 and 5-7 month core visits. The provision of information at 3-4 months, before complementary foods are

introduced, would allow parents time to make an informed decision about how their infant will be fed, and the 5-7 month visit would provide an opportunity to discuss any concerns. Verbal information from providers could be supported by printed resources and electronic tools such as phone apps and websites.

Finally, The Candidate suggests that it might be possible to combine the key points from the existing NZ MOH guidelines (Appendix A) with the BLISS intervention messages concisely and effectively, to produce guidelines which include information on the provision of safe foods, safe parental feeding practices, and how to deal with any unavoidable choking episodes which do arise. Potential revised guidelines could include:

- a list of concise, easy to remember 'General Principles' for reducing the risk of choking among all infants during the complementary feeding period
- a list of similarly concise 'Additional Recommendations for Baby-Led approaches' for families who choose to follow baby-led approaches with their infants
- a table describing foods which are thought to pose a choking risk, and how these can be modified to reduce risk in a) conventional infant feeding methods and b) baby-led approaches (this could be based on the current Table 20 from the NZ MOH Guidelines for Infants and Toddlers Aged 0-2 (Appendix A))
- a table which outlines the differences between choking and gagging, and how to identify and manage each event
- strongly stated advice to always have an adult with the infant when they eat, ideally sitting with the child.

It is recognised that this would altogether be a large amount of information which may be difficult for parents to remember. It is therefore suggested that the 'General Principles' are designed to be as all-encompassing as possible, and are presented as the most important information for all parents, regardless of the feeding method being followed.

6. Conclusions and future research

Infants in the BLISS group followed a version of BLW which was modified to reduce the risk of food-related choking and growth faltering. Although they were significantly more likely to gag, and gagged more frequently, than Control infants at the beginning of the complementary feeding period, BLISS infants did not choke more often than Controls. Furthermore, no cases of growth faltering were observed in either study group. Two BLISS infants and one Control infant were referred to the study paediatrician because they were potentially at risk of developing growth faltering, but none of these cases were found to be related to the method of complementary feeding.

These findings are reassuring because they suggest that concerns about choking and growth faltering are probably addressed by the BLISS approach to complementary feeding, although it is acknowledged that this was a relatively small study. It is important to remember that the results are not directly generalizable to infants following baby-led approaches (such as BLW) in the wider community, because their families would be unlikely to receive specific information about how to reduce the risk of either choking or growth faltering. In the future, if baby-led approaches to infant feeding are recommended on a population level, infant feeding advisories would ideally include guidelines on how to reduce the risk of choking and growth faltering in infants following these approaches. Furthermore, it is important to recognise that some of the BLISS study findings about food-related choking have implications for all parents and caregivers, regardless of the feeding method which they use with their infants. Although high percentages of infants in both groups were offered foods which were thought to pose a choking risk during weighed diet recording, the majority of foods which infants in the BLISS study actually choked on were not items which were thought to pose a choking risk. Additionally, parents did not consistently employ safe feeding practices, such as seating infants in secure locations and closely supervising all eating occasions. Future infant feeding advisories should therefore continue to emphasise the need for parents and caregivers to not only provide both safe foods and safe feeding environments, but also to have the knowledge and skills to identify and deal with any unavoidable choking episodes as they arise.

The BLISS study is the first randomised controlled trial to investigate the safety and efficacy of baby-led approaches to infant feeding, and to evaluate whether a BLISS approach alters the risk of choking and growth faltering among 0-12 month old infants. There is scope for further research to be conducted to investigate:

- whether the BLISS study findings are reproducible in other populations - the BLISS approach could be tested in another country, or in another part of New Zealand with different demographic characteristics to the Otago region
- whether any group differences are apparent when a similar study with a larger sample size, and therefore greater statistical power, is undertaken
- the most effective and economical ways of delivering safety messages about minimising the risk of food-related choking in infants, to all New Zealand parents and caregivers
- whether it is necessary to include messages about high-energy foods in baby-led approaches to infant feeding, or whether infants will receive enough energy for adequate growth without these messages.

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Appendix A:

Current information on food-related choking in babies and young children, as it appears in the New Zealand Ministry of Health Food and Nutrition Guidelines for Infants and Toddlers (Aged 0-2)¹

¹This is the information outlined in Appendix 13, which begins on page 151.

Food-related choking in babies and young children

People can choke on food at any age but young children, especially those less than three years old, are at greatest risk. Approximately 70–90 percent of all choking incidents reported are in children under three years, with foods being the most common cause of choking (Altkorn et al 2008, Altmann and Ozanne-Smith 1997, Despres et al 2006 and Goren et al 2005).

Sixteen children and young people (aged 0–24 years) died from foreign body inhalation (involving choking) in New Zealand during 2002–2009 (Hayman and Dalziel 2010). Thirteen deaths were in children under six years of age and nine of the deaths involved the inhalation of food, namely meat/ sausage, peanuts, apple and grapes.

European data found that for every child that dies from foreign body inhalation, another 10 are hospitalised (Zigon G et al 2006). Non-fatal choking incidents can cause severe acute and chronic health problems such as aspiration pneumonia, perforation to the airway or brain damage due to lack of oxygen.

The US Centers for Disease Control (CDC 2002) suggests that because complete removal of all choking hazards is unlikely, parents and caregivers should:

- be aware of the types of foods and objects that pose a choking risk for children
- become familiar with methods to reduce risk
- be able to treat choking in children.

Ozdemir et al (2005) also suggest parents must be educated about the importance of age and stage of development on feeding with solid food.

While people of any age can choke on food, young children choke on food more easily for a number of reasons (Byard et al 1996, Committee on Injury, Violence, and Poison Prevention 2010), including:

- the small diameter of their air and food passages (similar to the diameter of their little finger) which can be easily blocked by small objects
- their inexperience with moving food around in the mouth
- biting and chewing skills that are not fully developed
- a less effective cough mechanism to dislodge foreign bodies.

Byard et al (1996) suggest that although some young children are able to bite off food they may, due to age, lack the second molars that enable them to successfully grind the food prior to swallowing. Children don't normally have these second molars fully erupted into the mouth and functioning until they are over 30 months (two-and-a-half-years) of age. There are also significant individual, behavioural and anatomical differences among healthy children of the same age (Carruth and Skinner 2002). As a result, using age alone as a guide to judge eating competency can be problematic.

There are a number of high risk foods that are often associated with young children choking and most of these share common characteristics see Table 20. Making carers aware of them and how to make changes to reduce their risk is recommended.

Table 20: Characteristics and examples of foods that pose a high choking risk for children under five years

Food characteristics	Food examples	Choking risk	Changes to reduce risk
Small hard foods	Nuts Large seeds Hard dried fruit Pieces of raw carrot, celery or apple Food that break into hard sharp pieces, eg, crisps, corn chips and rice crackers Unpopped popcorn husks	Difficult for children to bite through and break down enough to swallow safely. Pieces can become stuck in children's airways	Avoid giving whole nuts, large seeds or hard dried fruit to children under the age of five Use thinly spread smooth peanut butter instead of whole or chopped nuts Carrot, apple and celery can be either cooked until soft or finely grated
Small round or oval foods	Grapes, berries, cherry tomatoes Raisins/sultanas Fruit with stones and large seeds or pips, eg, watermelon, small stone fruits Peas Lollies/sweets	Foods with these qualities can lodge in children's airways Children do not have the ability to chew small round hard, chewy or sticky lollies/sweets	Grapes, berries and cherry tomatoes can be halved or quartered or chopped smaller Soak raisins/sultanas to soften and cut in half if large Remove stones from fruits Peas can be squashed with a fork Small round hard or chewy and sticky lollies/sweets should not be given to children under the age of three years
Foods with skins or leaves	Chicken, sausages, saveloys, 'cherrios', frankfurters etc Stone fruits (eg, plums, peaches, nectarines) Apples and pears Tomatoes Lettuce and other raw salad leaves. Spinach, cabbage	Food skins are difficult to chew and can completely seal children's airways	Remove or peel skins before serving Chop up (to at least size of child's small finger nail and add to mashed food Remove stones from fruit Finely chop salad leaves Cook spinach and cabbage until soft and chop finely

Food characteristics	Food examples	Choking risk	Changes to reduce risk
Compressible foods	Sausages, saveloys, 'cherrios', frankfurters, hotdogs, etc Pieces of cooked meat Marshmallow Popcorn Chewing or bubble gum	Can conform to the airway shape and get wedged tightly	As above, remove skins before serving Cook meat until very tender Chop finely (to at least size of child's small finger nail) and add to mashed food Marshmallows and popcorn should not be given to children under three years Do not give chewing or bubble gum
Thick pastes	Chocolate spreads Peanut butter	Can form to the shape of a child's airway and stick to its side	Use thick pastes sparingly and spread evenly onto bread
Fibrous or stringy foods	Celery Rhubarb Raw pineapple	Fibres make it difficult for children to break up the food into smaller pieces	Peel the skin/strong fibres off celery and rhubarb Slice these foods thinly across the grain of fibres

One of the most important choking prevention measures is for carers to stay with and supervise young children while they are eating. Young children should learn not to play or run around while eating (Hayman and Dalziel 2010). Establishing a routine where young children sit while eating is recommended.

Parents and caregivers should never resort to forcing children to eat and should request a feeding assessment through their general practitioner for a child who repeatedly gags or chokes on age appropriate foods. An oral health assessment via the community oral health service may be needed if there is the child has discomfort with eating.

Although all care can be taken to prevent food related choking incidents they may still occur. Due to young children's greater vulnerability to accidental injuries it is recommended people caring for children, including parents, teachers and child care providers should learn cardiopulmonary resuscitation (CPR) and choking first aid for children (Ozdemir et al 2005, Committee on Injury, Violence, and Poison Prevention 2010).

For the key messages on minimising the risk of food-related choking in young children see section 4.4.4 Creating a safe, positive feeding environment.

For more information on food related choking see the Ministry of Health website: www.health.govt.nz

For information on choking first aid and cardiopulmonary resuscitation (CPR), see your Well Child Tamariki Ora Health Book or the Ministry of Health website www.health.govt.nz.

Appendix B:

Foods described as choking hazards in Rapley and Murkett's book 'Baby-Led Weaning'¹

¹Pages 114-115 of Rapley J, Murkett T. Baby-led Weaning. London, UK: Vermillion; 2008

“Some foods are particularly risky for babies and children because of their shape. Nuts are the most well-known example – **whole nuts (or large pieces) should be avoided until your child is at least three years old** because they can easily get lodged in a small child's windpipe. Fruits such as cherries should have the stone removed before they are offered to your baby and it is also a good idea to cut small round fruits, such as grapes and cherry tomatoes, in half. Remember to take care with cakes, casseroles and salads that may contain small, hard pieces of food. Bony fish is best avoided, too, and gristle should be removed from meat”.

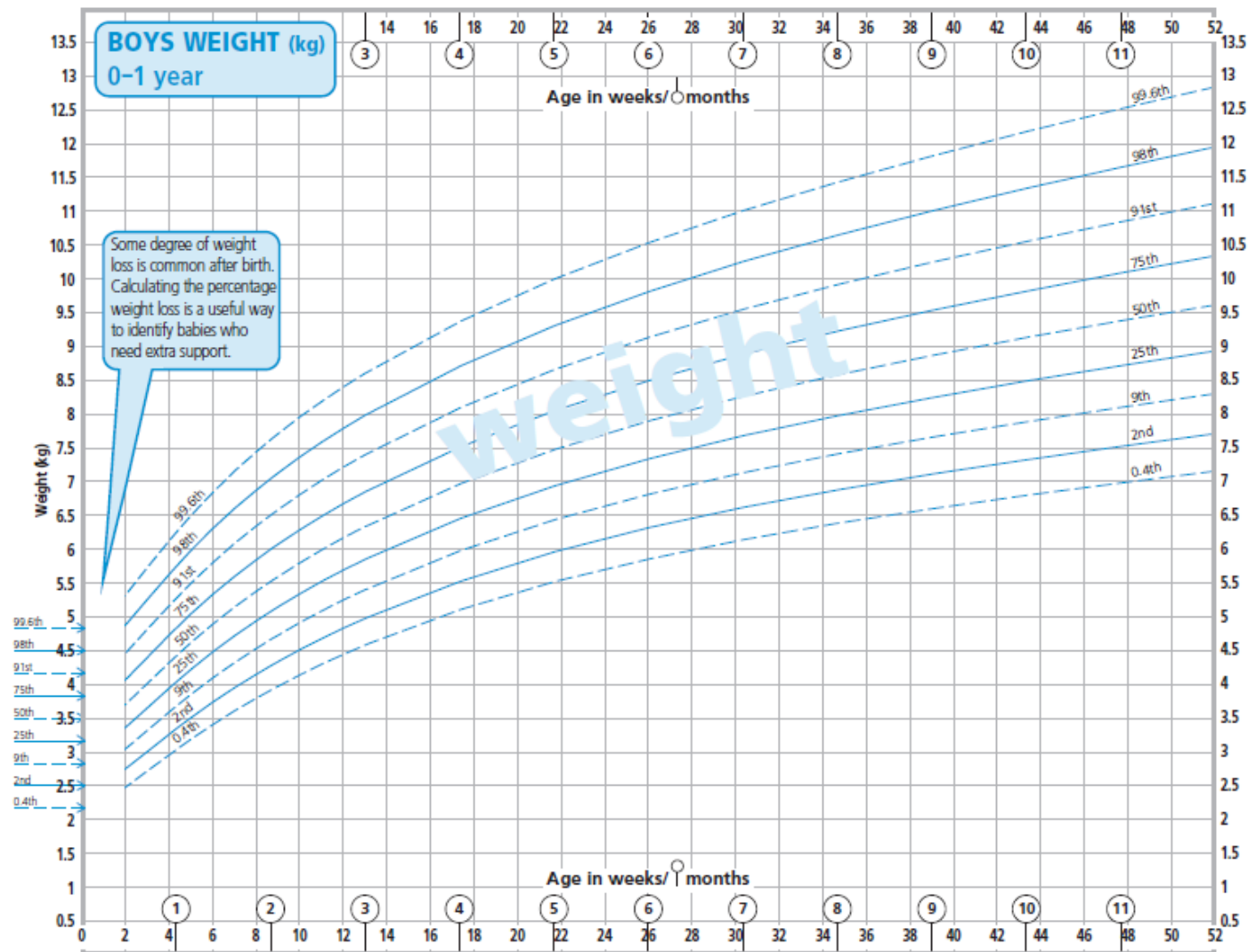
Appendix C:

Examples of NZ-WHO growth charts

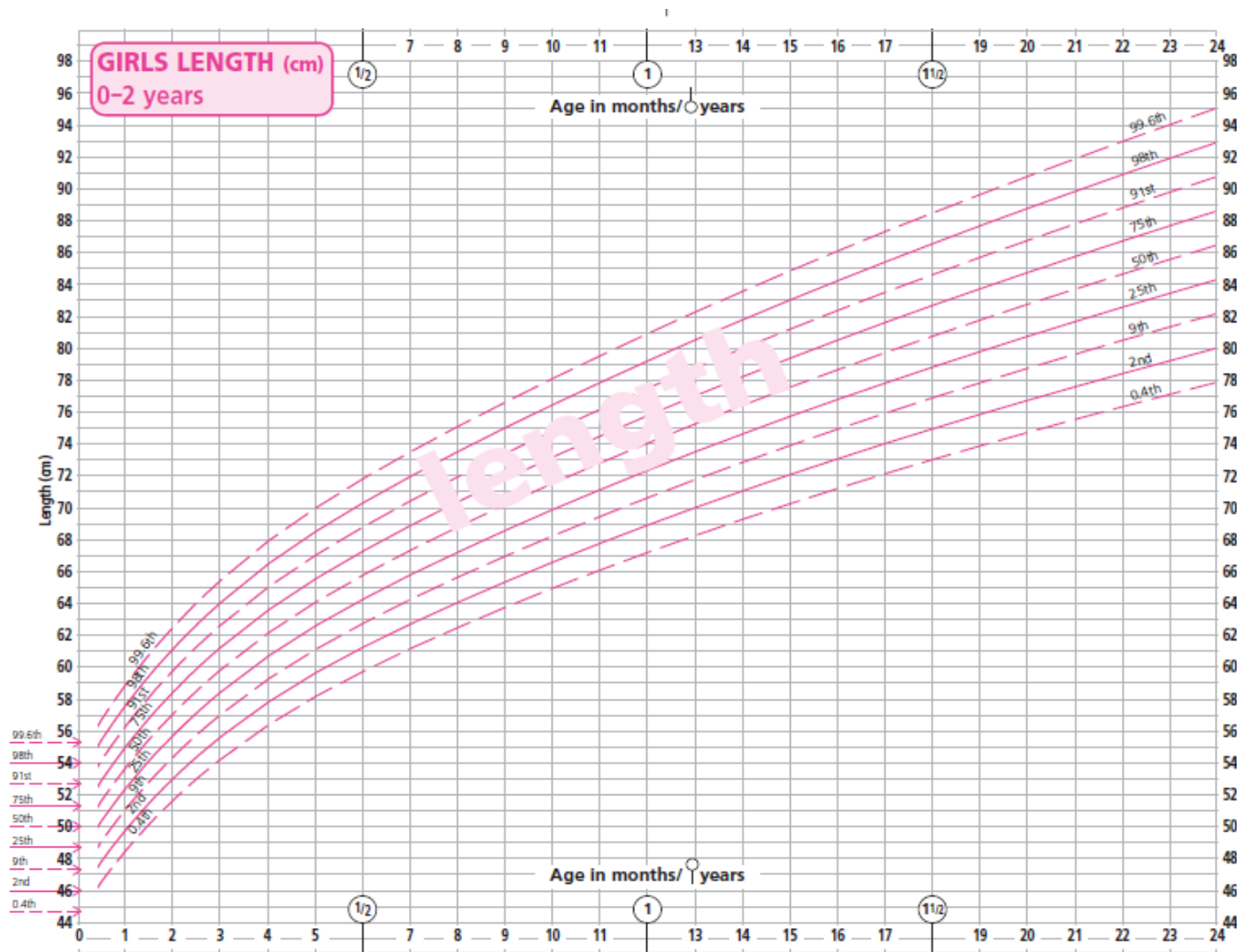
C1: Boys' weight 0-1 year.....

C2: Girls' length 0-2 years.....

C1: Boys' weight 0-1 year



C4: Girls' length 0-2 years



Appendix D:

Information pack for potential BLISS study participants

- D1.** Letter of invitation.....
- D2.** Information pamphlet.....

D1: Letter of Invitation

April 2013

Baby-Led Introduction to Solids (BLISS)

Dear (insert name)

We would like to invite you to take part in the BLISS study. This study will find out more about the way New Zealanders start their children on solid foods and how this affects their growth and health. You will find out about your baby's growth and whether they are getting enough nutrients as well as helping us improve the health of New Zealand babies.

If you decide to take part you will be one of the 200 families who are needed to answer these questions. We hope that most families having a baby in Dunedin from November 2012 to March 2014 will take part.

Please find enclosed an information sheet that describes the study in detail. We have been given ethical approval to send you this letter of invitation using contact details provided by the Queen Mary Maternity Unit. We will not share these details with any other party, and will destroy them if you choose not to take part in BLISS. Saying that you do not want to take part in the BLISS study will not affect the care you receive from your Lead Maternity Carer or Queen Mary in any way. If you decide after reading the information sheet that you do not wish to take part, please phone 479 4241 and leave a message to let us know. If we do not hear from you within two weeks, one of the team will contact you by phone to discuss the study further, answer any questions you may have and, if you would like to take part, arrange to visit you.

In the meantime, if you have any questions, please contact the research team:

Liz Fleming (BLISS Study Project Coordinator)
c/- Department of Human Nutrition
University of Otago
P O Box 56, Dunedin, New Zealand
Telephone (03) 471 6063
Mobile 022 192 7421
Email: bliss@otago.ac.nz

Many thanks for your time,

Kind regards

Dr Anne-Louise Heath, Associate Professor Rachael Taylor, and Professor Barry Taylor
Department of Human Nutrition, Department of Medicine, Department of Women's and Children's Health University of Otago, Dunedin.

D2: Information Pamphlet

How will my information be used?

Only the researchers will have access to the information. All data and questionnaires will be kept confidential. Group results of the project may be published, but not in a way that could identify any individual child or family.

What are the benefits if I take part?

There are lots of benefits to being in the BLISS study (whichever group you end up in):

- You will know that you are helping us improve the health of New Zealand infants and toddlers
- You will find out about your baby's growth
- You will find out whether your baby has enough iron
- You will find out if your baby is getting enough nutrients

What are the potential risks?

In the unlikely event of a physical injury as a result of participation in this study you will be covered by the accident compensation legislation (ACC).



Can I change my mind and withdraw from the study?

Deciding to take part in this study is entirely your choice. You do not have to take part in this study, and if you choose not to take part it will have no impact on your health care. If you do agree to take part you are free to withdraw from the study at any time, without having to give a reason and without any disadvantage to yourself of any kind.

What if I have any questions?

If you need an interpreter please tell us and we can provide one. You may have a friend, family or whānau support to help you understand the risks and benefits of this study and any other explanation you may need.

If there is a specific Māori issue/concern please contact Linda Grennell at 0800 377 766.

If you have any questions about our project either now or in the future please feel free to contact us:

Liz Fleming Ph 471 6063
Mob 0221 927 421
Email: bliss@otago.ac.nz

Investigators

Dr Anne-Louise Heath, Department of Human Nutrition
Associate Professor Rachael Taylor, Department of Medicine
Professor Barry Taylor, Department of Women's and Children's Health
University of Otago

Feeding our babies – are we getting it right?



Baby-Led Introduction to Solids (BLISS) – preventing obesity, protecting iron status

We would like to invite you to take part in an exciting new study about a new way to feed babies – Baby-Led Introduction to Solids (BLISS)

Why?

How babies are introduced to solid foods might be important for how they grow – now and as they are growing up. We want to look at different ways of starting babies on solid foods so that they grow well, enjoy healthy food, and get all the nutrients and foods they need – in a way that works for their parents and families.

November, 2012

Tell me more about the study

Many parents, especially first-time parents, look forward to their baby starting on solid foods. Currently most countries recommend that parents introduce solids from around 6 months of age starting with puréed foods, then gently moving to mashed and then chopped foods. However, a different way of introducing solids also exists: one where spoon-feeding isn't used and, instead, babies feed themselves – Baby-Led Introduction to Solids (BLISS).

What does this study involve?

The BLISS Study is a two-year study comparing the usual way of feeding babies (Standard Advice) with a different approach – BLISS. If you are in the BLISS group we will give you advice and support on how to feed your baby using this new baby-led approach. Neither you or the researchers can choose which group you are in so if you want to be in the study you have to be prepared to be in either the Standard Advice group or the BLISS group.



What happens in the Standard Advice group?

This is our "control" group so that we can see how New Zealand children grow. We will be in regular contact with you to see how things are going, and you will be free to choose the Well Child Tamariki Ora provider of your choice (for example, Plunket or Arai Te Uru Whare Hauora) in the same way that other New Zealand families do.

What happens in the BLISS group?

If you are in the BLISS group, you will be free to choose the Well Child Tamariki Ora provider of your choice (for example Plunket or Arai Te Uru Whare Hauora) in the same way that other New Zealand families do. In addition we will give you 7 extra visits to help with breastfeeding and Baby-Led Introduction to Solids (BLISS): one before birth and then when your baby is 1 week, and 1, 3, 5, 5.5, 7 and 9 months old.



What else would I be asked to do?

We have two main measurement visits when your baby is 12 and 24 months old. At these visits, we will measure baby's growth and ask you some questions about their feeding, mealtimes and how they are developing. We will contact you at 2 and 4 months to see how things are going. We would also like to measure their growth at 6, 7, 8, and 9 months to check that they are growing well, and ask you to fill out a brief questionnaire. When your baby is 7 and 12 months old we will lend you some kitchen scales and ask you to weigh and write down what they have to eat and drink for three days. When your baby is 1 year old, we would also like to do a blood test. The blood test will be carried out by very experienced paediatric nurses who use numbing gels to ensure minimal discomfort. We have done lots of these types of blood tests before with toddlers. We have some fantastic clinic rooms at the University with good parking for the appointments, or if you prefer, we can come to you in your home. You will be reimbursed for your travel costs.

This study has ethical approval from the Lower South Regional Ethics Committee

Appendix E:

Written informed consent

Consent form for the BLISS study

- I have read and I understand the information brochure for volunteers taking part in the BLISS study.
- I have had the opportunity to discuss the study and I am satisfied with the answers I have been given.
- I have had the opportunity to use Whānau support or a friend to help me ask questions and understand the study.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my future health care or that of my child.
- I understand that taking part in the blood test in this study is voluntary (my choice) and that I may decline the blood test and this will in no way affect my future health care or that of my child.
- I consent to my baby providing a blood sample when they are 12 months **YES / NO**
- If you consent to your baby providing a blood sample, would you like us to dispose of any blood left over in the standard manner? **YES / NO** or with an appropriate karakia? **YES / NO**
- I understand that my participation in this study is confidential and that no material which could identify me or my child will be used in any reports on this study.
- I have had time to consider whether to take part.
- I know who to contact if I have questions about the study
- I understand that when the study is completed, results of the study will be made available to me.
- I am happy to be contacted in the future to see if I might be interested in taking part in other related studies. **YES / NO**
- I agree to my GP being informed of my participation in this study and being notified about any abnormal results from my child's blood test. **YES / NO**

Name of GP

Address or Name of GP's practice

- I agree to my LMC being informed of my participation in this study. **YES / NO**

Name of LMC

Address or Name of LMC's practice

- I consent to information about my child's birth being transferred to the BLISS study researchers from my hospital and Well Child provider records. **YES / NO**

We will be contacting you via email or text - could you please give us

1. Your email address

2. Your mobile phone number

The name of your child's father (in case he comes to the visits) is

I _____ hereby consent to take part in this study

(Please print your full name)

Signature _____ Date _____

You have the opportunity to have an interpreter; please indicate in the table below whether you would like one and the language you would prefer:

English	I wish to have an interpreter	Yes	No
Maori	E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.	Ae	Kao
Cook Island	Ka inangaro au i tetahi tangata uri reo.	Ae	Kare
Fijian	Au gadreva me dua e vakadewa vosa vei au Io Sega Niuean Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu.	E	Nakai
Samoan	Ou te mana'o ia i ai se fa'amatala upu.	Ioe	Leai
Tokelaun	Ko au e fofou ki he tino ke fakaliliu te gagana Peletania ki na gagana o na motu o te Pahefika	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea.	Io	Ikai

Appendix F:

Protocol for the 5.5 month BLISS Advice visit

P16: 5.5 month BLISS visit

Copy no. ____

<i>Study:</i>	BLISS	<i>Version number:</i>	Version 1
<i>Prepared by:</i>	Liz Fleming	<i>Date prepared:</i>	July 2013

Objectives of measurement visit

Objective:

- R-12a Create good professional impression of study
- R-12b How things going with feeding - BM? FF? Solids?
Remind goal is milk feeding to 6 months if at all possible (if not then please
- R-12c call us)
- R-12d Any concerns about waiting to 6 months?
- R-12e Identify any issues & **record**
- R-12f Provide advice and support & **record**
- R-12g Discuss 6 month pamphlets
- R-12h **LEAVE:** 6 month pamphlets & folder
- R-12i Explain will be in contact at 7 months - but call if need any help
- R-12j What is best time to contact them in future?

Equipment required

Protocol: P16: 5.5 month BLISS visit

Other relevant documents: 5.5 month resources - Why Baby-Led Introduction to Solids, Getting Started, First Foods and First Food Recipes, Every Day Foods from 6 months, Bliss in a Nutshell, Safety When Starting Food
Satchel for resources
Baby rice 3 pkts per visit
Participant file
Map of address, if home visit

Steps - Before

- Book 5.5 month BLISS visit when prompted by DB task (see protocol P17: Phone call to arrange BLISS 5.5 and 6 month measure appointments).
- If home visit, book BLISS car.
- Ensure each participant has received a reminder phone call/text regarding date and time of session.
- Ensure you have all the 5.5 month resources and 3 packets of baby rice packed into the satchel

Steps - During

- Reintroduce/introduce self and convey our thanks for taking the time to see us today.
- Always try to use the baby's name to personalize the messages.
- Explain what is going to happen during this appt
 - "First of all, I'm going to explain what today's visit entails – first to see how things are going with feeding, then we will look at the resources we have made for starting solids in the BLISS way
 - 'Tell me how is it going with feeding, what BM? FF? Solids?
 - 'The BLISS study goal is milk feeding to 6 months if at all possible. If its not possible then please call us'
 - 'Do you have any concerns about waiting until 6 months?'
- Record any issues
- Provide advice and support & **record**
- **Discuss 6 month pamphlets**
- Ask about what foods may be convenient for their family

Firstly explain what BLISS is

- 'BLISS is a modified version of Baby-Led Weaning. BLISS still maintains the principles of BLW such as the infant joins in at the family meal and feeds themselves finger food rather than being spoon-fed purees however BLISS has a special focus on High Iron Foods.'

Resources:

Why –

- 'this is a resource that lets you know all about BLISS, the advantages of using this method and some of the things you may notice along the way. Through out this resource there are quotes from parents who have followed BLISS;'

Good things to point out are: baby knows how much to eat. You can all share meal times, together, you don't have to prepare the purees and take jars of baby food. But also its not a entirely fault free method. There may be mess and baby may take a while to actually start eating – but all of this is normal. There are some practical ways to reduce and contain mess such as plastic mats, and sweatshirt bibs.

Getting started –

- This resource is all about how you and your baby get started with BLISS.
- It is the **When, what and how of BLISS**.
- It has helpful advice about how baby should be seated, how much food to offer, what sort of foods to offer and tips on how to help your baby progress through BLISS and also what to do if your baby gets sick.

Talk to the participant about how they structure family meals, who cooks, what they have and when and where they eat.

First Foods and First Foods Recipes

- This is the resource where you can find all the food ideas for what you can offer (babys name) and how to prepare safe foods to offer to your baby.
- Each of these foods have a little symbol beside them (flip over to key and explain symbols).
 - High Iron = foods containing more iron
 - High Energy = Foods that are energy dense
 - Easy foods = foods that are easy for your baby to eat
- It is important that at each meal you are aiming to offer one of each of these
- What high iron foods do you think you may offer?

Get participant to choose one from the list, or comment on their suggestion.

- And for high energy foods? – what would be a high energy food from this list that you think might work well as a choice for your family foods?
- And an easy food?
- Great so that could be a meal for your baby.
- Next it tells you about some foods to avoid because they are unsafe or unsuitable for young babies. (Talk about each one briefly)
- Then it explains the size, shape and texture of the foods.
- The food should be in a **finger/chip** shape so baby can grab hold of one end and chew/suck the other end.
- There is also information about how best to cook your babys food. It's a good idea to remember that food should be soft enough to be able to be mushed on the roof of your mouth with your tongue but not so soft that the baby can squeeze it to pieces.

First Foods Recipes

- The back section of the books includes some recipes if you would like to try making your own hummus – this recipe has added iron (baby rice) or pate. A list of these recipes and other food ideas are in the First Foods resource section with the recipe page numbers recorded.

Everyday foods resource (three-column resource) to be pinned on the fridge

- This is a visual resource that can be pinned on the fridge to remind you of what foods you can offer your baby.
- It shows the high-iron, high energy and other foods in the three columns, some foods are both high energy and high iron (see the different colour text)
- Also the circled foods are foods that are good choices when baby is sick.'

Safety resource

It is important to inform parents but not to scare them. Focus on gagging and choking and being able to distinguish the difference. Also familiarize parents with CPR and what to do if choking happens. Some parents feel a lot better if they know they can have their infant eating on their knee instead of the high chair at the beginning of starting solids.

- 'All new parents get concerned about their baby choking when they first start to eat food.
 - This resource tells you how to keep your baby safe at meal times.
 - It also explains the difference between gagging and choking. (run through these)
 - At the back there are instructions to follow if your baby does choke – these come from the NZ Resuscitation Council and St John's Ambulance, Dunedin'
-
- **LEAVE:** 6 month pamphlets & folder
 - Explain will be in contact at 7 months - but call if need any help
 - Explain 7 month BLISS visit
 - "our next visit will be when (baby's name) is 7 months old" (*&length of appt?*)
 - "at this visit, we will have some new resources and recipes that are suitable for babies between 7-9 months"
 - 'What is best time to contact you in future? Or can we make the 7 month appointment today'

Steps – After

- Enter data from Participant tracking sheet into DB.
- Enter date for 7 month visit into BLISS calendar and set task for a text reminder prior to this appointment.


Appendix G:

BLISS intervention resources

The following were provided to participants at the 5.5 month BLISS Advice visit:

- G1:** Safety when starting food.....
- G2:** Examples of pages from the BLISS resource 'First Foods and Recipes'
- G3:** Everyday foods from 6 months.....

G1: Safety when starting food (provided to parents in booklet form)





Foods to avoid when introducing solids to your baby

- Foods that you can't mash on the roof of your mouth with your tongue
- Foods high in salt (a more than 300mg per 100g) and sugar (a more than 40g per 100g) (read labels carefully – many foods, such as jams, soups and gravy contain a lot of salt)
- 'Hot' foods and sticky/prepared/packaged meals
- Raw vegetables
- Raw eggs (whole or sliced)
- Under-ripe or hard fruit
- Crushed lozenges, mints unless each segment has been pierced
- Honey
- Shellfish, shark, mackerel
- Undercooked eggs
 - Eggs should be cooked until the white and yolk are firm
 - Dishes that contain eggs should reach an internal temperature of 100°C (which should be throughout the dish)
 - If you are boiling eggs in the shell, place eggs in a pot of cold water and cook for 15 minutes
- Whole nuts (peanut butter and other nut butters are fine)
- Popcorn
- Sausages, kebabs or any other similar food cut into rounds or 'cubes'


Remember to read our "Safety When Starting Food" resource.

Safety When Starting Food





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Some tips to make meal times safe times

- Make sure your baby is sitting up-right (not leaning back) to eat.
- Make sure you've tested baby's food by trying some yourself – you should be able to squash the food on the roof of your mouth with your tongue – especially in the early months.
- Never leave your baby alone with food.
- Don't let anyone except your baby put food into her mouth.
- Explain how Baby-Led Introduction to Solids works to anyone who is looking after your baby (you may like to use our "BLISS in a Nutshell" resource).
- Don't give your baby very small foods such as nuts, grapes, sweets, and fruits with stones (unless you've removed the stones).
- Only use thick plastic mats under baby's chair so you don't have thin plastic things in the house that could harm your baby.

I'm worried that my baby may choke if he feeds himself

For a long time parents have been encouraged to introduce finger foods at around six months to help their baby develop chewing skills – the difference with baby-led eating is that you don't spoon feed as well. It's still very important to follow our simple safety rules though.

Disclaimer: The information provided in this resource is intended only as a guide and is not intended to replace the advice of a healthcare professional or as a substitute for practical hands-on training. If you think your child may be choking we strongly recommend you seek medical advice immediately.



Giving CPR isn't hard to do

CPR uses chest compressions and rescue breaths to circulate oxygenated blood to the brain and vital organs until emergency medical help arrives.

Follow these steps:

If the baby is not breathing

If another person is present ask them to call an ambulance (dial 111) **NOW**.

If you are alone, give 1 minute of CPR, then take your baby with you to call an ambulance.

To perform CPR

1. Place the baby on your lap.
2. Open the airway: tilt the head back and lift the baby's chin.
3. Place your mouth over the mouth and nose of the baby and blow steadily to give 2 initial breaths.
4. Place two fingers or 1 thumb in the middle of the chest. Press down 1/3 of the depth of the chest. After 30 chest compressions give 2 breaths.
5. Continue cycle of 30 chest compressions and 2 breaths until emergency help arrives.



2. Lift chin

3. Cover mouth and nose
2 breaths

4. 30 chest
compressions

Sources include: NZ Resuscitation Council www.nzrc.org.nz/policies-and-guidelines
St John Ambulance, Dunedin, NZ

5

Recognizing the difference between choking and gagging

Many babies gag as they learn to regulate the amount of milk or solid food they are swallowing – but there is a big difference between gagging and choking, and learning to recognise the difference will make mealtimes more relaxed.

The **gag** reflex automatically closes off the throat and pushes the tongue to the front of the mouth. It's a reflex we have for our whole lives and is similar to the swallow, sneeze and cough reflexes. Your baby may gag a lot when you first introduce solid food to her diet as she learns to regulate the amount of food she can manage to chew and swallow at one time. And much like an adult, she is also likely to gag when she tastes food she doesn't like. Because a baby's gag reflex is much further forward on her tongue than an adult's she will gag more, but as she grows, this reflex will move further back. If your baby gags, it will be temporary and your baby will usually resolve it quickly.

Choking occurs when the airway becomes partially or completely blocked, preventing breathing. Generally, if your baby chokes, she will start to cough in an effort to clear her airways. This coughing and spluttering, which is alarming, is a sign that the baby is dealing with the problem. Soft foods are usually easily brought back up to the mouth with coughing but hard foods or other objects like small toys may require some additional help to dislodge (see "What to do if baby chokes" on page 4 of this resource).

2

What GAGGING looks like:

- His eyes may water
- He may push his tongue forward or out of his mouth
- He may be doing a retching movement to try and bring food forward in his mouth – he may even vomit

What to do if baby gags:

The best thing to do when your baby gags on food is to

- Watch him
- Allow him to deal with it in his own way as he is learning how to eat
- Talk to him using a relaxed tone of voice so as not to panic him. Reassure him that you are there.

What CHOKING looks like:

- Your baby may cough or gasp as she tries to draw in breath around the obstruction to clear it out
- Your baby may go silent
- She may make a struggling sound or raspy squeaking whisper as she tries to communicate her distress

What to do if baby chokes:

See the instructions on the next page of this resource.

3

What to do if baby chokes:

1. **DO** check to see if your baby is coughing, crying or breathing.
 - If she is crying or breathing, she is probably ok
 - If she is coughing, she may dislodge the obstruction on her own
 - If your baby is unable to dislodge the obstruction herself you may need to intervene

2. **DO NOT** try to dislodge the obstruction by putting your fingers in her mouth.

3. If breathing becomes laboured (noisy or difficult) at any stage take your baby with you to the phone and dial 111, ask for ambulance.

While you're waiting for help to arrive

(Your baby will instantly cry when the object is dislodged)

1. Lie her face down over your lap, ensuring her head is lower than her chest.
2. Give her one firm blow between the shoulder blades using the heel of your hand.
3. Check her mouth for the dislodged object.
4. Repeat steps 2 and 3 four times: one firm back blow, check mouth for dislodged object.
5. If she is still choking lie her on her back on your lap and, using two fingers, give her two chest thrusts in the centre of her chest, checking after each for the dislodged object.
6. If the object is still lodged, alternate between back blows and chest thrusts until emergency help arrives.

IMPORTANT! If your baby or child becomes unconscious, start CPR immediately (see next page of this resource).

NB: This advice is for babies under 12 months of age

4

G2: Example of pages from the BLISS resource 'First Foods and Recipes'

First Foods



These foods are some of the foods baby can eat at this age but there will be many more they will enjoy. Don't be afraid to explore a variety of foods with your baby, if you're unsure about offering a food refer to the "foods to avoid" section.

NB: When baby rice cereal is mentioned in this resource it is referring to Watties finely ground baby cereal, iron enriched.

- Offer one of these high iron foods with each meal
- ⚡ Offer one of these energy-rich foods with each meal
- ⊙ Offer one of these easy foods with each meal



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Recommended foods from 6 months

Vegetables (cut into thick sticks and cook until you can squash them on the roof of your mouth with your tongue)

- Pumpkin ⊙
- Carrot
- Broccoli
- Cauliflower
- Kumara ⚡ ⊙
- Potato ⚡
- Courgette

These foods are just some ideas, you can offer your baby any food as long as it is safe (check "foods to avoid" in this pamphlet) and they are able to pick it up.

Fruits

- Thick slices of avocado (not too ripe) ⚡
- Sliced banana, ⚡ ⊙ soft peach, soft apricot, soft nectarine, soft melon, soft pear, soft mango (skin and stones removed)

Toast fingers (remove crusts) topped with:

- Silky steak paté ■ ⚡ (see our "First Foods Recipes" resource, p.2)
- Beef and vegetable paté ■ ⚡ (see our "First Foods Recipes" resource, p.2)
- Liver paté ■ (see our "First Foods Recipes" resource, p.3)
- Baby rice ■ ⚡ ⊙
- Hummus ■ ⚡ (see our "First Foods Recipes" resource for hummus varieties, p.4-5)
- Mashed baked beans ■ ⚡
- Mashed avocado ⚡ ⊙
- Margarine and smooth peanut butter ⚡
- Mashed cottage cheese
- Margarine and cream cheese ⚡
- Mashed banana ⚡ ⊙
- Baby rice cereal plus avocado, hummus or cream cheese ■ ⚡ (see our "First Foods Recipes" resource, p.4)

Only offer liver paté once per week, and no more than 10g (2 teaspoons) per serving as it is high in salt and vitamin A. A good product to choose is "The Paté People; cracked pepper or French classic" or make your own.

Foods containing wheat should be introduced as soon as your baby starts solids at 6 months as this may reduce the risk of coeliac disease.

2

G3: Everyday foods from 6 months



Everyday Foods from 6 months

High Iron Foods ■

(Offer one of these foods at each meal)



Blue label = food also a Energy Rich food

Energy Rich Foods ⚡

(Offer one of these foods at each meal)



Red label = food also a High Iron food

Easy Foods ©

Steamed or boiled:
(see "First Foods Recipes" resource for cooking)



* Refer to "First Foods Recipes" resource for cooking and recipes

When your baby is sick offer some of the foods that have been circled (these are energy rich foods that are easy for your baby to eat) and remember to offer extra milk feeds. Your baby's appetite may be reduced when they are unwell so also offer their favourite appetising foods.

Appendix H:

BLISS study baseline questionnaire

Welcome and thank you for being part of the BLISS study.
This questionnaire is split into 2 sections and should take about 10 minutes to complete.
Please answer every question - *there are no right or wrong answers*.
Please ask the researchers if you have any questions - **thank you for your time**.

This section asks questions that will tell us how similar the people who are a part of BLISS are to other New Zealanders.

- 153

- 7** Which ethnic group(s) does your baby's father belong to? *Please tick all the boxes that apply*
- ☐ NZ European
 - ☐ Maori
 - ☐ Samoan
 - ☐ Tongan
 - ☐ Cook Island Maori
 - ☐ Niuean
 - ☐ Chinese
 - ☐ Indian
 - ☐ Other (such as Dutch, Japanese, Tokelauan). Please state: _____
- 8** What is your marital status?
- ☐ Single
 - ☐ Married/Civil union
 - ☐ Separated/Divorced/Widowed
 - ☐ Partner/De facto
 - ☐ Boyfriend/Girlfriend
- 9** What is your highest qualification? *Don't count qualifications that take less than 3 months of full-time study to get*
- ☐ Primary school
 - ☐ NZ School Certificate in one or more subjects *or* National Certificate level 1 *or* NCEA level 1
 - ☐ NZ Sixth Form Certificate in one or more subjects *or* National Certificate level 2 *or* NZ UE before 1986 in one or more subjects *or* NCEA level 2
 - ☐ NZ Higher School Certificate *or* Higher Leaving Certificate *or* NZ University Bursary/Scholarship *or* National Certificate level 3 *or* NCEA level 3
 - ☐ NZ trade certificate
 - ☐ Polytechnic diploma or degree
 - ☐ University undergraduate degree
 - ☐ University postgraduate degree
- 10** How many people live in your household? *Including yourself* _____
- 11** In addition to yourself, who else will your baby live with? *Please tick all the boxes that apply*
- ☐ Child's father
 - ☐ Your partner, but not child's father
 - ☐ Brothers or sisters (include step brothers/sisters)
 - ☐ Child's grandparents
 - ☐ Other relatives
 - ☐ Non-family members (eg. boarder)

- ☐ No-one else besides you
- 12** Have you taken any of the following supplements during this pregnancy? *Please tick all that apply and state the brand name.*
- ☐ Elevit
- ☐ Vitamin D *please state brand name: _____*
- ☐ Women's pregnancy vitamin *please state brand name: _____*
- ☐ Other *please state type (eg Iron supplement) _____*
please state brand name: _____

Questions 13 to 16 ask about your situation when **you became pregnant**

- 13** Were you in paid employment?
- ☐ No, I was not in paid employment
- ☐ I was employed part-time (include self-employed)
- ☐ I was employed full-time (include self-employed)
- 14** Were you studying at University or Polytechnic?
- ☐ No, I was not studying
- ☐ I was a part-time student
- ☐ I was a full-time student
- 15** How tall were you without shoes? *This is probably also your current height*
- _____ cm *or* _____ feet and _____ inches
- 16** How much did you weigh?
- _____ kg *or* _____ stone and _____ pounds *or* _____ pounds

Questions 17 and 18 ask about your baby's *biological father*

- 17** How tall is he without shoes?
- _____ cm *or* _____ feet and _____ inches
- 18** How much does he weigh?
- _____ kg *or* _____ stone and _____ pounds *or* _____ pounds

Section 2: Infant feeding

This section asks about how you plan to feed this baby, and if you have other children, how you fed them as babies.

19 Do you plan to breastfeed your child?

- ☐ Yes
☐ No *Please go to question 22*

20 At what age do you plan to stop **exclusively** breastfeeding your child? The term **exclusively breastfed** means that the infant receives **only** breast milk and nothing else except medicine. *Please give your answer as their age in days, weeks or months.*

_____ days or _____ weeks or _____ months of age
or

- ☐ Don't know

21 At what age do you plan to stop **all** breastfeeding? *Please give your answer as your infant's age in days, weeks or months.*

_____ days or _____ weeks _____ months of age
or

- ☐ Don't know

22 At what age do you plan to introduce solid foods? *Please give your answer as your infant's age in days, weeks or months.*

_____ days or _____ weeks or _____ months of age
or

- ☐ Don't know

Questions 23 to 25 are about starting your baby on solids.

23 At what age is it currently recommended that a child is first given solid foods? *Please give your answer as the child's age in days, weeks or months.*

_____ days or _____ weeks or _____ months of age
or

- ☐ Don't know

24 How do you plan to feed your baby when they first start eating solid foods?

- ☐ Spoon fed by adult
☐ Mostly spoon fed by adult, some baby feeding themselves
☐ About half spoon feeding by adult and half baby feeding themselves
☐ Mostly baby feeding themselves, some adult spoon feeding
☐ Baby feeding themselves

- ☐ Don't know or not yet decided

25 What type of food do you plan to feed your baby when they first start eating solid foods?

- ☐ All puréed or mashed foods (including cans or jars of baby food, or food you purée yourself)
- ☐ Mostly puréed or mashed food, some finger foods
- ☐ About half puréed or mashed food and half finger foods
- ☐ Mostly finger foods and some puréed or mashed foods
- ☐ All finger foods (for example carrot sticks, broccoli floret, sliced toast)

26 Do you have other biological children?

- ☐ No this will be my first child Please go to the end of the questionnaire
- ☐ Yes, 1 child
- ☐ Yes, 2 children
- ☐ Yes, 3 or more children

If you have more than one older child, please refer to the *youngest* child when answering questions 27 to 28.

27 How did you feed your **youngest** child when they first started eating solid foods?

- ☐ Spoon fed by adult
- ☐ Mostly spoon fed by adult, some baby feeding themselves
- ☐ About half spoon feeding by adult and half baby feeding themselves
- ☐ Mostly baby feeding themselves, some adult spoon feeding
- ☐ Baby feeding themselves

28 What type of food did you feed your youngest child when they first started eating solid foods?

- ☐ All puréed or mashed foods (including cans or jars of baby food, or food you purée yourself)
- ☐ Mostly puréed or mashed food, some finger foods
- ☐ About half puréed or mashed food and half finger foods
- ☐ Mostly finger foods and some puréed or mashed foods
- ☐ All finger foods (for example carrot sticks, broccoli floret, sliced toast)

Thank you for answering this questionnaire

Appendix I:

BLISS study calendar for recording choking and gagging on a day-to-day basis

Title page



BLISS Study Recording Calendar

Participant ID: _____

What GAGGING looks like:

- His eyes may water
- He may push his tongue forward or out of his mouth
- He may be doing a retching movement to try and bring food forward in his mouth – he may even vomit

What to do if baby gags:

The best thing to do when your baby gags on food is to

- Watch him
- Allow him to deal with it in his own way as he is learning how to eat
- Talk to him using a relaxed tone of voice so as not to panic him. Reassure him that you are there.

What CHOKING looks like:

- Your baby may cough or gasp as she tries to draw in breath around the obstruction to clear it out
- Your baby may go silent
- She may make a struggling sound or raspy squeaking whisper as she tries to communicate her distress

What to do if baby chokes:

See the instructions on the back page of this resource.

Recording page (each calendar contained five of these)

BLISS study calendar

Parents often worry about their baby gagging or choking when they start eating solids, but researchers know very little about how common it is – and what foods cause problems. Please use **2 stickers** at the **end of each day** – one for gagging, and one for choking. If baby chokes, please also fill out the choking questions. Please contact us later that day, or the next day, if your baby chokes and you get medical help for them.



	Monday		Tuesday		Wednesday		Thursday		Friday		Saturday		Sunday	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Has baby gagged on any food or drink today?														
Has baby choked on any food or drink today?														
<div style="display: flex; justify-content: space-around; align-items: center;"> If baby has choked ... ↓ ↓ ↓ ↓ ↓ ↓ </div>														
• What was the food?														
• What form was it in?	<input type="checkbox"/> Thin Liquid <input type="checkbox"/> Thick Liquid <input type="checkbox"/> Puréed <input type="checkbox"/> Mashed <input type="checkbox"/> Diced <input type="checkbox"/> Whole		<input type="checkbox"/> Thin Liquid <input type="checkbox"/> Thick Liquid <input type="checkbox"/> Puréed <input type="checkbox"/> Mashed <input type="checkbox"/> Diced <input type="checkbox"/> Whole		<input type="checkbox"/> Thin Liquid <input type="checkbox"/> Thick Liquid <input type="checkbox"/> Puréed <input type="checkbox"/> Mashed <input type="checkbox"/> Diced <input type="checkbox"/> Whole		<input type="checkbox"/> Thin Liquid <input type="checkbox"/> Thick Liquid <input type="checkbox"/> Puréed <input type="checkbox"/> Mashed <input type="checkbox"/> Diced <input type="checkbox"/> Whole		<input type="checkbox"/> Thin Liquid <input type="checkbox"/> Thick Liquid <input type="checkbox"/> Puréed <input type="checkbox"/> Mashed <input type="checkbox"/> Diced <input type="checkbox"/> Whole		<input type="checkbox"/> Thin Liquid <input type="checkbox"/> Thick Liquid <input type="checkbox"/> Puréed <input type="checkbox"/> Mashed <input type="checkbox"/> Diced <input type="checkbox"/> Whole		<input type="checkbox"/> Thin Liquid <input type="checkbox"/> Thick Liquid <input type="checkbox"/> Puréed <input type="checkbox"/> Mashed <input type="checkbox"/> Diced <input type="checkbox"/> Whole	
• Was baby feeding themselves?	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
• What happened?														

NB. Choking calendars also included information about choking first aid, which has already been included on page 149 (Appendix G).

Appendix J:

Weighed diet records

J1:	BLISS food diary.....
J2:	Away from home food diary.....
J3:	Childcare food diary.....
J4:	Laminated example sheet.....

(only key pages of the diary are provided here, as examples)

Things to record each day:

	What	When
1	Food Diary	When you are preparing, dishing and cleaning-up the food or drink
2	Description of Recipes Used	When you are cooking the recipe
3	End of Day Questionnaire	At the end of each day
4	Supplement Use	At the end of each day

On these days:

1.
2.
3.

Please try not to change what you give your child just because you are keeping a diary!

Thank you very much for your help



A) How to fill out your Food Diary

- Answer step 1 to step 6 for everything your child eats and drinks, when s/he eats and drinks it. Please don't rely on your memory at the end of the day.
- Record the amount and description of **ALL foods and drinks consumed** — all meals and all snacks.
- **Begin each new day on its labelled page**, (for example, Day 1). Remember each day starts at midnight and ends the following midnight. So please remember to record foods that occur at night.
- Use a **new line for each food or drink**. (You can use more than one line for a food or drink, but please start each new food or drink on a separate line).
- **Also please remember to include any additions to foods** (for example, tomato sauce, salad dressing, gravy).

Step 1	Step 2			Step 3		Step 4				Step 5		Step 6	
Time of day	Name of food or drink	Brand of food or drink	Cooking method	Weight of plate/mug	Weight of food/drink + plate/mug	Consistency of food/drink item				Food/drink was put in child's mouth by:		Weight of leftover + plate or mug	Estimation of what is left on plate
						Purée'd	Mashed	Diced	Whole	Parent	Child		
Please write down the time your child had something to eat, or drink, including am or pm .	Describe the food or drink.	Name the brand.	If the food was cooked write down how it was cooked (roasted, steamed, fried). If the food was coated in something or you added things like sauce or butter please record this. If a recipe was used to make a dish please write "see recipe" and write out the recipe on the page labelled "Recipes".	1) Weight an empty plate or mug using the scales provided. 2) Write down the weight.	1) Place the first food or drink on the plate/ mug on the scales. 2) Write down the weight. 3) If you add several foods to the same plate you will need to write down the weight after each food is added.	Please tick the option that best describes the consistency of the food/ drink item.				Please tick the option that best describes who put each food/drink in child's mouth.		After your child has eaten their meal place the same plate or mug with all the leftovers on the scales and write down the total weight of the food or drink and the plate or mug.	Estimate how much of each food was left over (for example, 1 tablespoon mince, half the potato). "Leftovers" are everything your child doesn't eat so please try and scrape everything your child didn't eat back on to the plate and weigh.

B) How to describe recipes

Example:

Step 1	Step 2	Step 3	Step 4	Step 5
Name of recipe	Amount of each ingredient including any water added (eg: 3 medium carrots, 500g lean beef mince, 1 onion, 60g water etc)	Cooking method	Proportion of recipe served to your child	Time of day served
Home-made mince	300g standard beef mince (browned in 1 tablespoon olive oil) 50g onion, diced 60g carrot, diced 1 clove garlic, minced 60g beef stock (Campbells) 30g tomato sauce (Watties) 60g diced potatoes 40g diced kumara 40g frozen mixed vegetables (Watties) 60g water 5g white flour	Mince was stewed in a small pot with the lid on	One tenth (1/10)	6 pm

D) How to fill out your End of Day Questionnaire

Table 1: Please answer **all steps** (Step 1 - 4).

Table 2: Please answer Part 1 **or** Part 2, depending on you child's food and drink intake today.

: If you answer Part 2, please fill in **all the steps** (Step 1 - 4).

Table 1

Step 1	Step 2	Step 3	Step 4			
Date	Day of week	Is this a typical eating day for your child?	Is your child unwell (for any reason)?	If unwell, did this influence your child's appetite?		
2 March 2013	Thursday	Yes <input type="radio"/> No <input checked="" type="radio"/>	Yes <input checked="" type="radio"/> No <input type="radio"/>	No <input checked="" type="radio"/>	Yes - Decreased appetite	Yes - Increased appetite

Table 2

An example filled out by the parents of a 9 month old

How did your child's meals compare to the family meals today?

Part 1				Part 2			
				Step 1	Step 2	Step 3	Step 4
				Breast milk/ formula and food	Child ate meal with at least one other adult: (Both were eating but food may be different.) Yes or No	Meal Ingredients	Meal Preparation (Eg: texture of meal, length and method of cooking, size of food pieces)
						Exactly the same or Almost the same or Similar or Different / Mostly different	Exactly the same or Almost the same or Similar or Different / Mostly different
Breakfast	Did not have this meal today	Was with another adult at this meal time	Breast milk or formula only	✓	✓	"Similar" could be serving some of the same ingredients, but leaving out, or changing others.	"Almost the same" could be cooking vegetables a little longer, or cutting foods into finger sized pieces.
Lunch		✓					
Evening meal				✓	✓	"Almost the same" could be having the same main ingredients but leaving out some of the spices, or swapping rice for pasta.	"Different" could be serving roast vegetables and chicken for the family meal, and puréed vegetables and chicken for your child.

6

Date: _____
Day of week: _____

[illegible]

If your child has finished eating for the day, please remember to fill out the end of day questionnaire and supplement use on pages 11 and 12.

8

End of Day Questionnaire - Day 3

Table 1

Step 1	Step 2	Step 3		Step 4				
Date	Day of week	Is this a typical eating day for your child?		Is your child unwell (for any reason)?		If unwell, did this influence your child's appetite?		
		Yes	No	Yes	No	No	Yes - Decreased appetite	Yes - Increased appetite

Table 2

How did your child's meals compare to the family meals today?

[illegible]

Supplement Use — Day 3

(a) Did your child take any supplements today? Include anything you consider to be a supplement to your child's diet (e.g., multi-vitamin, etc.).

No ☐ (please go to page 27)
Yes ☐

(b) If yes, please record the following:

Type of supplement (e.g., cod liver oil): _____

Brand name (e.g., Smith's): _____

Amount (number of mls, drops, tablets, capsules, etc.) taken (e.g., 5mls): _____

(c) If yes, does the supplement contain iron or zinc? (check the label)

No ☐
Yes ☐

If yes, please record the type of iron (e.g., ferrous fumarate, ferrous sulphate and anything else with the words "iron", "ferric" or "ferrous" or "zinc" (e.g., zinc sulfate) and the amount of iron or zinc per tablet (e.g., 10mg, etc.):

Type of iron (e.g., ferrous sulphate): _____ Amount per dose (e.g., 7mg in 5ml): _____ Number of doses: _____

Type of zinc (e.g., zinc sulfate): _____ Amount per dose (e.g., 7mg in 5ml): _____ Number of doses: _____

THE INTERVIEWER WILL HELP YOU FILL IN THIS PAGE IF YOU ARE NOT SURE - please keep the bottle or packet

J2 **Away From Home Food Diary** (given to participants in booklet form)



BLISS Food Diary

Away from Home Booklet



Thank you!

Remember if you have any questions please contact us. You can email or call our answer-phone and we'll get back to you.



- Please use this booklet if you are leaving the house and will be unable to weigh foods.
- Remember we are NOT looking for a "healthy" diet. We need to know what children actually eat and how they eat.



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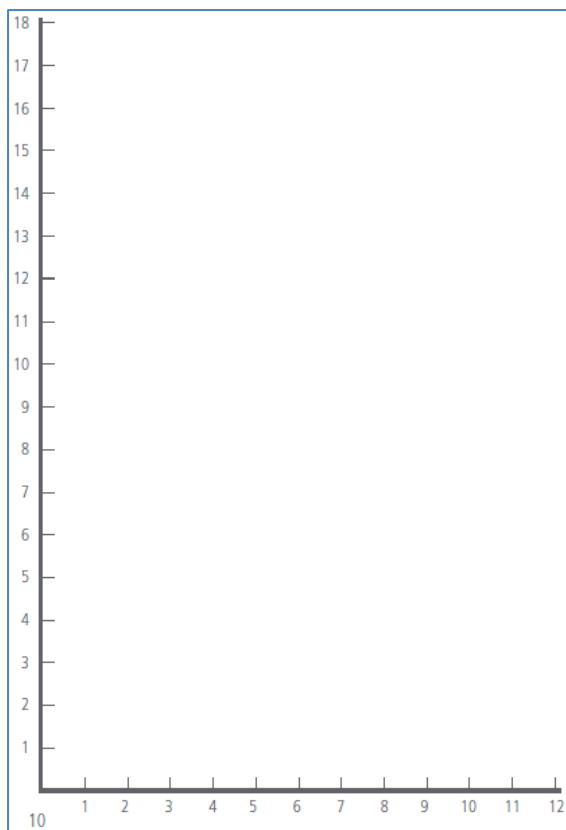
Thank you very much for your help

version 30.6.2013

Day 1 Date: _____
Day of week: _____

[illegible]

Adapted from Adult Nutrition Survey 08/09

[illegible]

3

Day 2

Date:

Day of week:

[illegible]

Takeaway Foods Estimation Guide



4

9

Please record an estimated amount in the "weight of food or drink" column.

- **HOUSEHOLD MEASURES** – Household measures like cups, tablespoons and teaspoons can be useful. Please tell us whether it was a heaped or level amount.
- **WEIGHTS MARKED ON PACKAGES** – Use the weight marked on canned or packet foods e.g., half a 220g can of baked beans, one 60g pottle of yoghurt.
- **RULER** – Foods such as cheese, cakes and meat can be measured using the ruler provided on page 10, e.g., slice of luncheon sausage 8cm x 4cm x 1mm (remember to give length, width and depth!).
- **CIRCLES** – Round foods such as biscuits and muffins can be measured using the circles provided on page 11, e.g., one muffin 6cm circle x 7cm high (height estimated using the ruler).
- **BREAD** – Tell us the number and the size of the slices e.g., sandwich, medium, or toast slice.
- **FRUIT** – Tell us whether the piece of fruit is small, medium or large. Alternatively you could use the circles for round fruit such as mandarins.

Page 9 has photographs of commonly eaten takeaway foods. Please write down the weight from the photograph that best describes the amount of food your child was served and write it in the "Weight of food or drink" column. Your child might not have exactly the amount in the photos so feel free to tell us if she had "two x 40g pizza".

Remember: We are NOT looking for a "healthy" diet. We need to know what children actually eat and how they eat it.

[illegible]

Childcare Food Diary

We know how busy ECE Centres can be - Thank you very much for filling out the Information on these pages, we really appreciate your support of the parents' participation in this study.

If you would like to know more about the Baby-Led Introduction to Solids study (BLISS), our website is: bliss.otago.ac.nz. If you have any comments or questions, then please feel free to contact the study on (03) 471 6063 or bliss@otago.ac.nz.

Thank you!

J4 Laminated Example Sheet

An example filled out by the parents of a 14 month old toddler

Step 1 Time of day	Step 2			Step 3		Step 4				Step 5		Step 6	
	Name of food or drink	Brand of food or drink	Cooking method	Weight of plate/ mug	Weight of food/drink + plate/ mug	Consistency of food/drink item				Food/drink was put in child's mouth by:		Weight of leftover + plate or mug	Estimation of what is left on plate
						Purée	Mashed	Diced	Whole	Parent	Child		
7:30am	Breastfeed 15 minutes	Write down every time your child has a breast or formula feed. For breast milk please write down the duration of the breastfeed. For formula please fill out all the columns.							✓	✓	✓	Tick both 'parent' and 'child' for breast feeds.	
	1 slice white bread toast slice	Tip Top	toasted	115g	135g				✓		✓		almost all
	Butter, salted	Mainland			140g				✓		✓		"
	Marmite	Sanitarium			142g				✓		✓	127g	"
	Baby food, peach, apricot and semolina	Watties	microwaved	80g	200g	✓					✓	100g	
10am	Fruit cake	If you don't have your scales with you please estimate the amount.			2 match boxes				✓		✓	Tick 'child' if you pre-load the spoon, but they put the spoon in their mouth.	
	Bobby banana				small			✓			✓		
	Water				2 sips				✓	✓			
	Breastfeed 10 minutes								✓	✓	✓	Please weigh the total amount of food left over + weight of plate or mug.	
12pm	Medium fries 45g (from Away from Home booklet pg 9)	McDonalds							✓		✓	1/8 leftover	
	Small lemonade	McDonalds							✓		✓	1/3 leftover	
3pm	Breastfeed 20 minutes								✓	✓	✓		
	Home-made mince (see recipe)			115g	145g				✓	✓		155g	one tsp
6pm	Potato		boiled		195g		✓			✓			1/2
	Butter				197g				✓	✓			
	Peas, frozen		boiled		211g	✓				✓			none
	Fruit juice = Orange and mango	Just Juice		42g	210g				✓		✓	44g	
	Ice cream = Vanilla	Tip Top		80g	140g				✓	✓		86g	
8pm	Infant formula = follow-on formula	Smiths		50g	250g				✓	✓		90g	
	Water	tap		90g	470g				✓	✓	✓	205g	

If your child drinks water out of a bottle, remember to weigh their full drink bottle when you fill it up and any leftovers before you refill it or empty it.

For liquids, if your child is holding the cup/bottle, tick 'child'. If an adult is holding the cup/bottle, tick 'parent'.

Of the total amount that is left over please tell us how much there is of each food (for example, half the mince, half the potato, no peas).

Appendix K:
BLISS study measurement protocol

P19a – Anthropometric Measurements

<i>Study:</i>	BLISS	<i>Version number:</i>	Version 5
<i>Prepared by:</i>	MH, RT, BJT, ALH	<i>Date prepared:</i>	30 Nov 2013
<i>Original title:</i>	P19a_Procedure for identification & management of growth faltering		

Objectives

To undertake anthropometric measurements (weight, length) of children at 6, 7, 8, 9, 12 and 24 months of age

Equipment required

Protocols: P19: 6-month measurement visit
P19a: Anthropometric measurements (this protocol)
P19b: Identification & management of growth faltering

Other documents: Anthropometry Data Sheet
BLISS letterhead paper to leave baby's measurements with parent

Equipment: Equipment Bag
Infant weight scale
Batteries (6 x 1.5V type AA)
Length board
Calibration weight
Calibration rod
Sanitary sheet (for use on length board & scales)
Hand sanitizer
Pencil (for recording results on data sheet)
Eraser
Nappies
Baby Wipes
Bag (to keep rubbish in one place & ensure it is taken away at the end of visit)

Measuring equipment

All measuring equipment must be highly accurate, precise, sturdy and portable.
All equipment should be checked prior to each measurement:
- Scales must be checked with the calibration weight before each set of measurements
- Length board must be checked with the calibration rod before each set of measurements

Harlow Healthcare Rollameter (UK) (range 30-110 cm) with digit counter readings precise to 1mm



Seca weighing scales (Model 334, Hamburg, Germany) - portable electronic scale that have taring capability and measures in 5 gram increments up to 10kg, and 10g increments up to 20kg (accurate to $\pm 10g$).

Steps – Before

See protocol **P19: 6-month measurement visit** for steps before visit.

Steps – During

General principles

1. The anthropometrist's confidence and poise is important for reassuring both the mother and child, and includes maintaining eye contact and talking to the child in a calm, reassuring voice.
2. Measurements should be taken and recorded twice.
3. It is important to follow the same technique and protocol during successive measurements.
4. Any measurements falling outside the maximum allowed differences should be repeated and entered in designated boxes on the Anthropometry Data Sheet.
5. Data should be entered on the sheet using a pencil.
6. Record the measurement immediately after it is read - have your pencil and data sheet near you.
7. Record the measurement directly onto the data sheet. The more times the measurement is copied, the more chances of error there are.
8. Record measurements clearly and neatly, the same way every time.

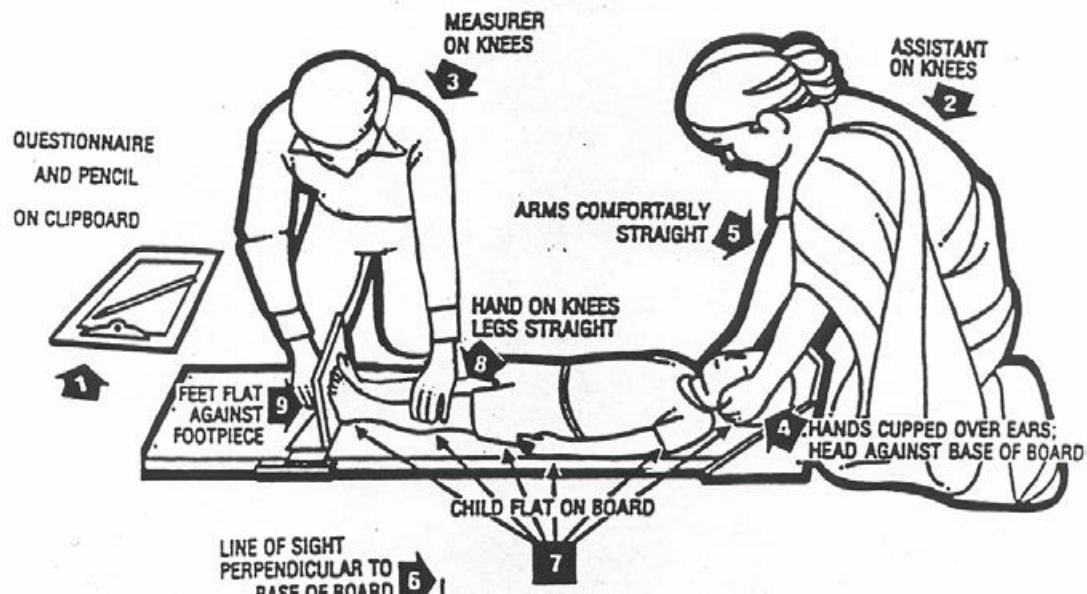
- Introduce yourself
- Thank for taking time to meet today
- Remind the participant not to tell measurers what group they are in
- Ensure that the parents understand what is happening and that they are comfortable with the process
- Go over what will be measured:
 - Infant weight (and (sometimes) length).
- Explain that measurements will only be used for this study and will be kept confidential.
- We can give them a copy of the measurements if they wish.
- Ask parent to remove the child's clothing down to a singlet and the nappy provided.

The best order to carry out the measurements is:

- 1) Length 1
- 2) Weight 1
- 3) Length 2
- 4) Weight 2
- 5) Repeat Length and/or Weight if necessary

Infant length

1. Explain to the mother the procedure for measuring length - the mother will be required to help with measurement and to soothe and comfort the child.
2. Place the length board on a flat hard and stable surface.
3. Use the 90cm calibration rod to check that the length board is measuring correctly. Allow an error of $\pm 2\text{mm}$ (i.e. 0.2cm). If the length board is not measuring the rod correctly, please record the measurement it gives, record the infant length, and adjust the board after the appointment.
4. Cover the length board with a sanitary sheet for hygiene and for the baby's comfort.
5. Ask the mother to remove hair ornaments and lay the child on his back against the fixed headboard, compressing the hair.
6. Quickly position the head so that the crown touches the headboard. ***An imaginary vertical line from the ear canal to the lower border of the eye socket is perpendicular to the board*** (Frankfort Line). The child's eyes should be looking straight up. Ask the mother to move behind the headboard and hold the head in this position.
7. Kneel by the side of the length board where you can see the measuring tape and move the footboard.
8. Check the child lies straight along the board and does not change position. Shoulders should touch the board, and the spine should not be arched. The arms rest against the sides of the trunk.
9. Hold the child's legs down with one hand and move the footboard with the other. Apply **gentle** pressure to the knees to straighten the legs as far as they can go without causing injury (minimum pressure). If both legs cannot be held in position, measure with one leg in position and put a note in the comments.
10. While holding the knees, pull the footboard against the child's feet. The soles of the feet should be flat against the footboard, toes pointing upwards.
11. Record the child's length in cm to the last completed 0.1cm.
12. After weight has been measured, take a repeat measurement. If the two measurements disagree by equal to or more than **0.7cm** then take a third measurement.



Infant weight

1. Explain to the mother the procedure for measuring weight - the mother will be required to soothe and comfort the child.
2. Place the scales on a flat, hard, even surface. Be sure there is adequate light to read measurement.
3. If battery symbol or 'bAtt' appear in the display, you should change the batteries before measuring.
4. Use the calibration weight to check that the scales are measuring correctly (Allow an error of $\pm 0.010\text{kg}$ (i.e. 10g). If the scales are not measuring the calibration weight correctly, please record the measurement it gives, record the infant weight, warn the parent that it might be necessary to reweigh on another occasion, and report problem to the growth team after the appointment.
5. Place a sanitary sheet on the scales for hygiene and for the baby's comfort.
6. Tare the scales by pushing the TARE key and waiting until 0.000 appears on the display (NB: this is only possible if the infant weighs less than 10.000kg. If the baby weighs more than 10kg, then (a) record the weight of the child (and sanitary sheet), then (b) the weight of the sanitary sheet alone and (c) record both values on the Anthropometry Data sheet so that the weight of the sanitary sheet can be subtracted from the child's weight).
7. Ask the mother to remove all the child's clothes down to a singlet and the nappy provided if this hasn't already been done.
8. Use a blanket to cover the child in cold weather.
9. Place baby on scales and record measurement to the nearest 0.1kg.
10. After the second length measurement has been taken, take a repeat measurement. If the two measurements disagree by more than **0.1kg** then take a third measurement.

Maximum allowable differences between the two measurements

Measurement	Maximum allowable difference
Weight	0.1kg
Length	0.7cm

Record measurements for parent

- Record average weight and length (i.e. one single value for each) on BLISS letterhead paper with date measured, and “Thank you from the BLISS team”.

Steps – After

- All recorded measurements are entered into the database.
- Use protocol **P19b: Identification & management of growth faltering** to identify growth faltering.
- File Anthropometry Data Sheet in anthropometry data sheet file.

- Adjust length board** if required (i.e. if measurement of calibration rod is out by more than $\pm 2\text{mm}$ (i.e. 0.2cm)):
 - Put calibration rod on length board.
 - Draw footboard up to the end of the rod.
 - Using a Phillips screwdriver, loosen the large screw and washer holding the adjustment plate at the end of the board opposite the headboard.
 - Slide the adjustment plate until the calibration rod is being measured correctly.
 - Tighten the screw so that the plate doesn't move.
- If this needs to be done more than once, then inform the growth team.

- If the **scales** measure the calibration weight incorrectly by more than $\pm 0.010\text{kg}$ (i.e. 10g) then inform the growth team and use the other set of scales until the problem has been resolved.

Frequently Asked Questions

1) What should my infant's weight or length be (what is normal)?

This is best seen on the growth charts in your “**Well Child**” book. If you want, I can give you a copy of the measurements and you can put them in your child's “Well Child” book.

Appendix L:

The step-by-step process of the development of the list of foods thought to pose a choking risk to infants

The step-by-step process:

1. Firstly, the foods listed by five international groups were compared, as outlined in Table 1.
2. Any food item which was listed as a potential choking risk by 4/5 or 5/5 groups was automatically included in the final list of foods thought to pose a choking risk to infants. Any item over which there was a lack of agreement between lists, or which the MSc candidate had queries about, was discussed with a paediatric speech language therapist with experience in choking in children before a final decision about its' inclusion (or otherwise) was made.
3. Table 2 describes the rationale behind the inclusion of specific items on the list, while Table 3 outlines the reasons behind the exclusion of other items.
4. It was particularly difficult to determine whether different types of 'meat' were thought to pose a choking risk to infants. All meat listed in weighed diet records therefore had to be considered on a case-by-case basis, with guidelines for this process outlined in Table 4. Only meats which were thought to pose a 'High or Likely High' risk were included in the final analysis.
5. The final list of foods which were thought to pose a choking risk to infants, used in this thesis for comparison with weighed diet records, is outlined in Table 5.

Table 1: Comparison of foods currently listed as potential choking hazards for infants and young children by five international groups

Food	Group Name				
	New Zealand Ministry of Health ¹	Cameron et al ² (BLISS Pilot Study)	American Academy of Pediatrics ³	Nicholls et al ⁴	Department of Health, Australia ⁵
Large vegetables	Raw carrot, celery, lettuce, raw salad leaves, spinach, cabbage, tomatoes	Raw vegetables (eg carrot, celery, salad leaves)	Chunks of raw vegetables	Raw vegetables	Raw carrot, celery
Small vegetables	Peas	Peas, corn			
Large fruit	Raw apple, pears, stone fruit (eg plums, peaches, nectarines), raw pineapple, rhubarb	Raw apple		Fruit chunks	Raw apple
Small fruit	Cherries, grapes, berries, cherry tomatoes	Cherries, grapes, berries, cherry tomatoes	Whole grapes	Whole grapes	
Dried fruit	Hard dried fruit, raisins, sultanas	Dried fruit (raisins, cranberries)			
Nuts and seeds	Nuts, large seeds (eg those from watermelon and small stone fruits)	Whole nuts	Nuts, seeds	Nuts, seeds	Nuts, seeds
Crackers, crisps and chips	Rice crackers, potato crisps, corn chips	Rice crackers, potato crisps, corn chips			Corn chips

Table 1 continued: Comparison of foods currently listed as potential choking hazards for infants and young children by five international groups

Food	Group Name				
	New Zealand Ministry of Health ¹	Cameron et al ² (BLISS Pilot Study)	American Academy of Pediatrics ³	Nicholls et al ⁴	Department of Health, Australia ⁵
Popcorn	Popcorn, unpopped popcorn husks		Popcorn	Popcorn	Popcorn
Confectionary	Lollies/sweets Marshmallow	Lollies (sweets, candy)	Hard or sticky candy	Sticky hard candy	Lollies
Processed meat sausages & similar products	Sausages, saveloys, cheerios, frankfurters etc	Saveloys, hot dogs	Hot dogs	Hot dogs	Sausages & hot dogs
Other meat	Chicken, pieces of cooked meat		Chunks of meat or cheese		Tough or chewy pieces of meat
Spreads	Peanut butter, chocolate spreads		Chunks of peanut butter	Chunks of peanut butter	
Chewing gum	Chewing or bubble gum		Chewing gum	Chewing Gum	

1. Ministry of Health. Food and Nutrition Guidelines for Healthy Eating for Infants and Toddlers (aged 0-2): A background paper – partially revised December 2012. Wellington, New Zealand: Ministry of Health, 2008.
2. Cameron SL, Heath A-LM, Taylor RW. Development and pilot testing of Baby-Led Introduction to SolidS - a version of Baby-Led Weaning modified to address concerns about iron deficiency, growth faltering and choking. *BMC Pediatrics* 2015; 15: 99.
3. American Academy of Pediatrics, Committee on Injury, Violence, and Poison Prevention. Policy Statement - Prevention of Choking Among Children. *Pediatrics* 2010; 125: 601-607.
4. Nichols BG, Visotcky A, Aberger M, Braun N, Shah R, Tarima S, et al. Pediatric exposure to choking hazards is associated with parental knowledge of choking hazards. *Int J Pediatr Otorhinolaryngol* 2012; 76: 169-173.
5. Australian Government Department of Health. Food Safety- Allergies, Choking and Food Handling. Internet (cited 17 February 2016). Available from: <http://www.health.gov.au/internet/publications/publishing.nsf/Content/gug-children-toc~gug-children-safety>

Table 2. Rationale behind the inclusion of items on the list of foods thought to pose a choking risk to infants

Food	Rationale
All raw vegetables	Raw vegetables were listed by 5/5 groups, with 'raw carrot' and 'raw celery' specified by all three Australasian groups. The AAP guidelines were less specific, listing undefined 'chunks' of raw vegetables. The SLT advised that the exact choking risk associated with raw vegetables depends on both the hardness and the presentation of each individual vegetable; she went on to suggest that all raw vegetables be considered to pose a choking risk for this work. The candidate kept a list of the various raw vegetables offered to infants during weighed diet recording, for reference.
Peas	Although peas are usually cooked until soft and were only specified by 2/5 groups in Table 1, they were included on the advice of the SLT because they are a small round shape and could lodge in a child's airway if swallowed whole. It is also possible that some families may offer these fresh from the garden, or even frozen as a snack, rather than cooked, which increases the associated choking risk.
Corn	Although corn was only specified by two of the groups in Table 1, the SLT recommended that it was included because corn kernels are small, hard and of a roughly circular shape.
Raw apple	Raw apple was only specifically listed by 3 of the groups in Table 1, however the SLT and the candidate considered its inclusion to be justified because it is a very hard food, and had been identified as the most commonly choked on food among infants following BLW in a content analysis study.
Raw pineapple	Raw pineapple was only specifically listed by 1 of 5 groups in Table 1. However, the SLT considered it to be a hard, fibrous food which would possibly be served in 'chunks' and therefore could present a choking risk.
Hard crackers	Crackers were thought to pose a choking risk to infants in the BLISS Pilot Study (Cameron et al) and are also listed in the NZ MOH guidelines. The SLT advised that the choking risk associated with crackers was dependent on their hardness: hard crackers (such as rice and water crackers) present a risk because pieces can break off in an infant's mouth and be inhaled, but soft crackers or similar items (such as cruskits) which dissolve in the mouth do not present a risk. Because the weighed diet records included brand names, it was possible to distinguish between hard and soft crackers and therefore determine which ones posed a choking risk to infants.

Table 2 continued: Rationale behind the inclusion of items on the list of foods thought to pose a choking risk to infants

Food	Rationale
Corn chips	Corn chips were listed by 3 of the 5 groups in Table 1, and their inclusion in the final list was encouraged by the SLT because they are very hard.
Crisps	Crisps were only listed by the New Zealand groups in Table 1 (NZ MOH and Cameron et al), but as with corn chips, their inclusion in the final list was endorsed by the SLT because of their hardness.
Rusks	Rusks were not listed by any of the groups in Table 1, but were included on the advice of the SLT who recognised that they are often very hard and do not dissolve easily in an infant's mouth; it is therefore possible that pieces could break off and be inhaled.
Dried fruit (raisins, sultanas etc)	These were only listed by the NZ MOH and Cameron in Table 1. However, the SLT recommended that they be included in the final list because they are often small and round, they may be sticky, and when they are served alone they can be difficult to control in the mouth, thereby increasing the risk of inadvertent swallowing and choking.
Whole nuts	Nuts were recognised by all five groups in Table 1, and were therefore automatically included in the final list.
Large seeds	Seeds were recognised by 4/5 groups in Table 1, but there was an overall lack of specificity about whether all seeds (regardless of shape or size) presented a risk. The SLT pointed out that very small seeds (such as chia seeds) would not have the capacity to block a child's airway and should not be considered a choking risk; her suggestion was to consider any seed the size of a pumpkin seed or larger as presenting a choking risk. However, she did not think it was necessary to count watermelon seeds due to their flat shape, and in most cases weighed diet records did not include details about whether seeds had been removed from watermelons and pips from small stone fruit. These were therefore omitted from the final list of foods which were thought to pose a choking risk.

Table 2 continued: Rationale behind the inclusion of items on the list of foods thought to pose a choking risk to infants

Food	Rationale
Whole cherries	These were only listed by the New Zealand-based groups in Table 1, but were included in the final list because they are small and round with a small hard stone. (Cherries which have been cut and destoned do not present a risk).
Whole grapes	Identified as a risk by four groups of the groups in Table 1, and therefore automatically included in the final list. (Grapes which have been halved or quartered before serving are not a choking risk).
Small berries	The lists of the NZ MOH and Cameron et al both included 'berries' but did not include specific examples of which berries presented a risk. The SLT suggested that any berry the size of a raspberry or smaller, which was served whole, would be capable of lodging in a child's airway. 'Small' therefore refers to berries of such a size.
Whole cherry tomatoes	These were only listed by the two New Zealand groups in Table 1, but the SLT and the candidate felt that their inclusion in the final list was justified because they are small and round and could become lodged in a child's airway.
Small, hard and/or sticky lollies	Confectionary of this type was unanimously recognised as a choking risk by all five groups in Table 1 and was therefore automatically included in the final list.
Marshmallow	Although only specifically listed by the NZ MOH, marshmallows are likely to be small and round with a compressible nature and were therefore considered to present a choking risk. It is possible that some groups would consider marshmallows to be 'sticky' candy.
Sausages	Sausages or at least one similar product with a compressible nature and a circular shape (such as saveloys, cheerios, hot dogs and frankfurters) were listed as a choking risk by all five groups in Table 1 and were therefore automatically included in the final list.
Battered fish	Battered fish was not specifically listed by any of the groups in Table 1. However, it was included in the final list on the advice of the SLT, whose rationale was that some batter can be very hard and difficult to manage in the mouth, especially when consumed in conjunction with much softer fish.

Table 2 continued: Rationale behind the inclusion of items on the list of foods thought to pose a choking risk to infants

Food	Rationale
Popcorn (including unpopped husks)	Popcorn was recognised as a choking risk by 4/5 groups in Table 1 and therefore automatically included in the final list. While unpopped popcorn husks would not be expected to be served alone, they were included in the final list in recognition that they may sometimes be served inadvertently with popped husks.
Chewing gum	Chewing gum was only listed by 3/5 groups in Table 1, possibly because the remaining two groups may not have considered it a 'food' as such. It was included in the final list because of its sticky nature and ability to occlude airways.
Meat (excluding sausages, and unbattered fish)	Meat was listed by 3/5 groups in Table 1. However, there was a lack of specific information about the type of meat which presented a choking risk, and the SLT advised that there were a number of factors which would influence whether different meats would pose a choking risk. Consequently, a separate analysis was undertaken for meat (see Table 4).
Other considerations	
Pureed and mashed foods	Any food listed above which was served in a pureed or mashed form was <u>not</u> counted as a choking risk, because the qualities (such as hardness or rigid round shape) which created the risk were altered by the process of pureeing or mashing.
Recipes	If an infant was offered a food listed above as part of a recipe, the item was counted if it was expected that it would have retained the characteristics which meant that it was thought to pose a choking risk, and/or if it was expected that the infant would be able to pick the item out of the dish and place it (alone) in their mouth.
Other foods	If the MSc candidate suspected that an item listed in a WDR posed a choking risk, but the item was not listed above, the food in question was discussed with the SLT in order to make a final decision about whether it was thought to pose a choking risk.

Table 3: Rationale behind the exclusion of items from the list of foods thought to pose a choking risk to infants

Food	Rationale
Pears	Pears were only listed by 1/5 groups in Table 1. The texture of pears ranges from soft to hard; there was no way of identifying the texture of each pear listed in the weighed diet records, and counting all pears as choking risk foods would have been likely to result in an overestimation of choking risk. They were therefore omitted from the final list.
Large stone fruit (eg plums, peaches, nectarines)	Only 1/5 groups in Table 1 (the NZ MOH) listed large stone fruit as posing a choking risk. The NZ MOH also recognised that these did not present a risk if the skin and stones were removed; unfortunately, study participants were not asked to describe whether they had removed fruit skins and stones in the weighed diet records, although it was likely that most parents did do this. Counting all large stone fruit listed in the weighed diet records would therefore have been likely to result in an overestimation of choking risk, so they were therefore omitted from the final list.
Rhubarb	The NZ MOH were the only group in Table 1 to specifically list rhubarb as posing a choking risk; they recognised that it could be served safely if the skin and any fibrous material was removed. Rhubarb was omitted from the final list because none of the other organisations listed it as a high risk food, and because participants were not asked to describe whether they had removed the skin and any fibrous parts of rhubarb in the weighed diet records, again therefore leading to a potential overestimation of risk.
Watermelon	The NZ MOH were the only group in Table 1 who specifically listed watermelon (as an example of a food with large seeds). Participants were not asked to specify whether seeds were removed from watermelon before serving when keeping weighed diet records. The SLT did not consider watermelon seeds to be a high risk food because they are quite flat, rather than spherical in shape. Watermelon, and watermelon seeds, were therefore excluded from the final list.
Peanut butter, chocolate spreads	The NZ MOH listed peanut butter and chocolate spreads, but suggested that they could be served safely if used sparingly and spread evenly onto bread. Two of the organisations in Table 1 listed 'chunks' of peanut butter as choking risk foods. Serving peanut butter in chunks was not expected to be common in the study population. Consequently, peanut butter and chocolate spreads were not included on the final list, but the candidate was to make a note of any cases where 'chunks' of spreads were offered to infants.
Chunks of cheese	The AAP were the only group in Table 1 to list these, and they did not define 'chunks' or 'cheese' (which could be hard, soft, or even spreadable such as cottage cheese). Given this lack of specificity and that no other organisation considered cheese to be a choking risk food, it was omitted from the final list.

Table 4: Categorisation of ‘meat’ listed in weighed diet records, by level of choking risk

Level of risk	Food examples	Rationale
Low or likely low	Pureed meat	Pureed foods are generally recognised as being of low choking risk.
	Mashed meat	Mashed foods are generally recognised as being of low choking risk.
	Meat in commercial baby food	Commercial baby food which is specially prepared for this age group is expected to contain soft meat in appropriately sized pieces.
	Meat described as casseroled, stewed or slow-cooked	These cooking methods are expected to result in tender meat, which presents a low choking risk.
	Meat described as ‘whole’ in the ‘form’ section of the WDR	‘Whole’ meat was assumed to be in pieces large enough for the child to hold onto, i.e. strips of meat which were long enough to be hand-held.
	Minced meat made into items such as meatballs/meatloaf/koftas	These items are expected to be quite soft and able to be mashed against the roof of an infant’s mouth.
	Minced meat included as part of a composite dish such as lasagne, spaghetti bolognese or Shepherd’s Pie	These dishes would be expected to be soft and to form a moist, manageable bolus in the mouth.
	Processed deli meats such as ham, luncheon, belgium	These are unlikely to be tough or chewy, or served as ‘chunks’, and were included in this category on the advice of the SLT (unless served as a pizza topping – see below).

Table 4 continued: Categorisation of 'meat' listed in weighed diet records, by level of choking risk

High or likely high	Mince fried on its own	Mince fried alone may have hard knobbly pieces and will be harder to manage than moist mince meals (such as Shepherd's Pie or lasagne).
	Meat described as 'diced'	Participants were not asked to include the size of pieces of diced meat in weighed diet records.
	Meat toppings on pizza (e.g. bacon)	Pizza toppings are usually hard when pizza is removed from the oven, and may be picked off the pizza by an infant and eaten alone (rather than as part of a bolus in the mouth).
Unable to determine	Any type of meat where the WDR record does not provide sufficient information to determine consistency	Weighed diet record does not include sufficient information to determine whether or not these meats were likely or unlikely to have presented a choking risk.

Table 5. Final list of foods considered to pose a choking risk to infants

Food item	Further details about the form of the food that poses a choking risk
Battered fish	Hard batter (most likely in commercial deep-fried fish) was considered to pose a risk.
Berries	Berries \geq raspberries in size were not considered to pose a risk. Berries cooked until soft in baked goods such as muffins were not considered to pose a risk because they become soft and lose their rigid shape.
Chewing gum	Any chewing gum was considered to pose a risk.
Corn	All types of corn (kernels, creamed, on cob) were considered to pose a risk unless served in a puréed or mashed consistency or as part of a commercial, texture-modified baby food.
Corn chips	Corn chips in any form were considered to pose a risk.
Crisps	Hard crisps (i.e. conventional potato crisps) probably pose a greater risk than softer crisps (e.g., cassava crisps); however, for consistency and because of the wide range of crisps available, all crisps were considered to pose a risk.
Dried fruit	Dried fruit served alone (e.g., raisins) probably pose a greater risk than dried fruit that is part of an item that forms a bolus in the mouth (e.g., a muffin containing dried fruit); however, dried fruit in such composite items was also considered to pose a risk because of its potential to maintain shape, size and stickiness during cooking. Dried fruit that had been rehydrated to a large size and soft consistency (e.g., sultanas in a slow-cooked casserole) was not considered to pose a risk.
Hard crackers	Crackers which easily dissolve in the mouth were not considered to pose a risk. Hard crackers do not dissolve easily and may break into hard pieces in the mouth; these were considered to pose a risk.
Marshmallow	Marshmallow-based confectionery such as 'chocolate fish', as well as uncoated marshmallows, were considered to pose a risk because the sticky nature of the marshmallow in such products poses a risk.

Table 5 continued. Final list of foods considered to pose a choking risk to infants

Food item	Further details about the form of the food that poses a choking risk
Meat	Meat which was served puréed, mashed, or 'whole' (large pieces which the baby can grasp to self-feed) was not considered to pose a risk. Similarly, meat which had been cooked until very tender (as would be expected in a soup, slow-cooked meal or similar) was not thought to pose a risk. Small pieces of diced meat (requiring a spoon to feed), meat with the skin on, and small hard pieces of meat (such as cubes of meat cooked on a pizza) were considered to pose a risk.
Peas	Peas served puréed or mashed were not considered to pose a risk. Whole peas were considered to pose a risk even if served within a larger item (e.g., casserole) because of their potential to be picked out and eaten whole.
Popcorn	This included unpopped popcorn husks, which may be served unintentionally with popped husks.
Sausages and similar products	'Similar products' included frankfurters and hot dogs. These were considered to pose a risk unless (a) the skin was removed <u>and</u> (b) they were not presented in very small (requiring a spoon to feed) or coin-shaped pieces.
Raw apple	Raw apple sealed in a net bag was not considered to present a risk as the child cannot separate the apple from the net bag in the mouth. Apple which was cooked until soft or which was puréed or mashed was not considered to pose a risk.
Raw vegetables	All raw vegetables were considered to pose some degree of risk, dependant on their hardness, unless they were sealed in a net bag. Any vegetables which had been cooked until soft, or puréed or mashed, were not considered to pose a risk.
Baby rusks	Rusks were considered to pose a risk due to the potential for hard pieces which are not easily dissolvable to break off in the mouth. Both commercial and home-made products were considered to pose a risk.

Table 5 continued. Final list of foods considered to pose a choking risk to infants

Seeds	Small seeds (e.g., chia seeds) were not considered to pose a risk but larger seeds (≥pumpkin seed size) do.
Small/hard/sticky candy	All small/hard/sticky candy was considered to pose a risk.
Whole cherries	Cherries which had been halved and the stone removed were not considered to pose a risk.
Whole cherry tomatoes	Cherry tomatoes which had been halved were not considered to pose a risk.
Whole grapes	Grapes which had been halved were not considered to pose a risk.
Whole nuts	Nut butters were not considered to pose a risk.
<i>Other Considerations</i>	
Pureed and mashed foods	Any food listed above which was served in a pureed or mashed form was not counted as a choking risk.
Recipes	If an infant was offered a food listed above as part of a recipe, the item was counted if it was expected that it would have retained the characteristics which deemed it a choking risk, and if it could be separated from the rest of the dish.
Other foods	If the MSc candidate suspected that an item listed in a WDR posed a choking risk, but the item was not listed above, the food in question was discussed with the SLT in order to make a final decision about whether to count it as a choking risk.

Appendix M:

Other infant eating locations reported by parents during the BLISS study

The eating locations listed as 'Other' in Table **4.10** included both restrained and unrestrained locations. At each time point, they were described as:

6 months	n
baby chair on the floor	30 (14 Control, 16 BLISS)
floor	23 (8 Control, 15 BLISS)
booster seat	3
baby-oriented piece of equipment ¹	16
transportation equipment ²	8
family furniture ³	4
other miscellaneous locations ⁴	4
7 months	n
baby chair on the floor	40 (9 Control, 31 BLISS)
floor	40 (n=18 Control, 22 BLISS)
booster seat	2
baby-oriented piece of equipment ¹	8
transportation equipment ²	9
family furniture ³	3
other miscellaneous locations ⁴	4
8 months	n
baby chair on the floor	15 (6 Control, 9 BLISS)
floor	56 (n=25 Control, 31 BLISS)
booster seat	2
baby-oriented piece of equipment ¹	7
transportation equipment ²	9
family furniture ³	5
other miscellaneous locations ⁴	5
11 months:	n
baby chair on the floor	27 (n=9 Control, 18 BLISS)
floor	63 (n=29 Control, 34 BLISS)
booster seat	2
baby-oriented piece of equipment ¹	3
transportation equipment ²	10
family furniture ³	4
other miscellaneous locations ⁴	4

¹ such as a bouncer, walker, rocker or exersaucer ² such as a pram, capsule or carseat

³ such as a sofa or adult-sized chair ⁴ such as 'standing up', bed, outside on grass or sand, in bath, in parent's 'arms'

Appendix N:

Growth trajectories for infants who met growth trigger 3 (only) during the BLISS study

Table 1: Case studies of infants who met Growth Trigger 3 (only) at least once between 6-12 months of age

ID (group)	Age (months)	Referral to paediatrician	Reason for meeting trigger	Paediatrician advice	Follow-up findings	End point (as advised by paediatrician)
1337 Control	6-7	×	Weight decreased by 20g.	Please advise of weight at 8 months. Extra measure at 10 months.	Despite repeated attempts, family could not be contacted at 8 months. Between 7 and 9 months, weight increased by 70g (a gastrointestinal illness had affected feeding for 10 days within this timeframe). Weight increased by 400g between 9 and 10 months.	Satisfactory gain between 9 and 10 months; return to standard study measurement schedule.
1439 Control	6-7	×	Weight decreased by 20g (an ear infection had affected feeding).	Please advise of weight at 8 months. Extra measure at 10.5 months.	Weight increased by 110g between 7 and 8 months, despite infant being unwell with further ear infections. This information was not reported to the paediatrician. Weight increased by 280g between 8 and 9 months, which the paediatrician was notified of. Weight increased by 400g between 9 and 10.5 months (the latter weight was taken by a Plunket nurse).	Satisfactory gain between 9 and 10.5 months; return to standard study measurement schedule.
1122 Control	6-7	×	Weight decreased by 20g.	Please advise of weight at 8 months.	Weight increased by 480g between 7 and 8 months.	Satisfactory gain between 7 and 8 months; continue with standard study measurement schedule.

Table 1 continued: Case studies of infants who met Growth Trigger 3 (only) at least once between 6-12 months of age

ID (group)	Age (months)	Referral to paediatrician	Reason for meeting trigger	Paediatrician advice	Follow-up findings	End point (as advised by paediatrician)
0370 BLISS	6-7	×	No weight change (0.0g). (Family had moved out of the Dunedin area between 6 and 7 months. 7 month weight was taken by a Plunket nurse in their new location).	Please advise of weight at 8 months.	Weight increased by 790g between 7 and 8 months.	Satisfactory gain between 7 and 8 months; continue with standard study measurement schedule (because the family had moved, further weights were to be taken at Plunket and emailed to a BLISS research assistant).
0482 Control	7-8	×	Weight change between measurements was 0.00kg.	Please advise of weight at 9 months.	Weight increased by 680g between 8 and 9 months.	Satisfactory gain between 8 and 9 months; continue with standard study measurement schedule.
1071 Control	7-8	×	Weight decreased by 60g.	Please advise of weight at 9 months. Extra measure at 10.5 months. Please advise of weight at 12 months.	Weight increased by 120g between 8 and 9 months. Weight increased by 190g between 9 and 10.5 months. Paediatrician was not notified of 12 month weight. Notification of 24 month weight, which showed an increase of 3.12kg between 12 and 24 months, was provided.	Satisfactory increase between 12 and 24 months; no follow-up required after study completion.
0865 BLISS	7-8	×	Weight decreased by 90g (a gastrointestinal illness and a chest infection had affected feeding).	Please advise of weight at 9 months.	Weight increased by 710g between 8 and 9 months.	Satisfactory increase between 8 and 9 months; continue with standard study measurement schedule.

Table 1 continued: Case studies of infants who met Growth Trigger 3 (only) at least once between 6-12 months of age

ID (group)	Age (months)	Referral to paediatrician	Reason for meeting trigger	Paediatrician advice	Follow-up findings	End point (as advised by paediatrician)
1021 BLISS	7-8	×	Weight decreased by 200g.	Please advise of weight at 9 months.	Weight increased by 700g between 8 and 9 months.	Satisfactory increase between 8 and 9 months; continue with standard study measurement schedule.
0823 BLISS	7-8	×	Weight decreased by 60g.	Please advise of weight at 9 months.	Weight increased by 350g between 8 and 9 months.	Satisfactory increase between 8 and 9 months; continue with standard study measurement schedule.
1716 BLISS	7-8	×	Weight decreased by 20g.	Please advise of weight at 9 months.	Weight increased by 400g between 8 and 9 months.	
				Please advise of weight at 12 months.	Weight increased by 1.41kg between 9 and 12 months.	Satisfactory increase between 9-12 months; continue with standard study measurement schedule.
0340 Control	8-9	×	Weight decreased by 10g.	Extra measure at 10 months.	Extra measure was never conducted. Infant weight increased by 680g between 9 and 12 months, and the infant did not meet any growth triggers at 12 months.	Not reviewed by paediatrician due to extra measure being missed, and due to infant not meeting any growth triggers at 12 months of age.
0340 Control	8-9	×	Weight decreased by 10g.	Extra measure at 10 months.	Extra measure was never conducted. Infant weight increased by 680g between 9 and 12 months, and the infant did not meet any growth triggers at 12 months.	Not reviewed by paediatrician due to extra measure being missed, and due to infant not meeting any growth triggers at 12 months of age.

Table 1 continued: Case studies of infants who met Growth Trigger 3 (only) at least once between 6-12 months of age

ID (group)	Age (months)	Referral to paediatrician	Reason for meeting trigger	Paediatrician advice	Follow-up findings	End point (as advised by paediatrician)
0614 Control	8-9	×	Weight decreased by 90g.	Extra measure at 10 months.	Weight increased by 180g between 9 and 10 months.	Satisfactory gain between 9 and 10 months; return to standard study measurement schedule.
1090 Control	8-9	×	Weight decreased by 80g.	Extra measure at 10.5 months. Please advise of 12 month weight. Extra measure at 18 months. Please advise of 24-month weight.	Weight increased by 240g between 9 and 10.5 months. Weight increased by 560g between 10.5 and 12 months. Weight increased by 1.73kg between 12 and 19 months (latter measurement was delayed). Weight increased by 950g between 19 and 24 months.	Satisfactory gains in second year of life; no further follow-up required after study completion.
1376 Control	8-9	×	No weight change (0.0g). (Family had moved out of the Dunedin area between 8 and 9 months, so the 9 month weight was taken by a Plunket nurse in their new location).	Extra measure at 10 months. Extra measure at 11 months.	Weight decreased by 220g between 9 and 10 months; however, infant had been unwell with bronchiolitis which had affected their appetite. Despite repeated attempts, family could not be contacted for extra measure. They were also unable to be contacted at 11, 12 and 24 months.	Family were lost to follow-up.
1505 Control	8-9	×	Weight decreased by 60g (a gastrointestinal illness had affected feeding).	Extra measure at 10 months.	Weight increased by 660g between 9 and 10 months.	Satisfactory gain between 9 and 10 months; return to standard study measurement schedule.

Table 1 continued: Case studies of infants who met Growth Trigger 3 (only) at least once between 6-12 months of age

ID (group)	Age (months)	Referral to paediatrician	Reason for meeting trigger	Paediatrician advice	Follow-up findings	End point (as advised by paediatrician)
0896 BLISS	8-9	×	Weight decreased by 50g (infant had been unwell with a virus for 2.5 weeks).	Extra measure at 10 months. Please advise of weight at 12 months. Extra measure at 15 months. Please advise of weight at 24 months.	Weight increased by 540g between 9 and 10 months. Weight increased by 250g between 10 and 12 months. Weight increased by 720g between 12 and 15 months. Weight increased by 2.25kg between 15 and 24 months.	4Satisfactory gain between 15 and 24 months; no further follow-up required after study completion.
1098 BLISS	8-9	×	Weight decreased by 60g.	Extra measure at 10 months.	Weight increased by 920g between 9 and 10 months.	Satisfactory gain between 9 and 10 months; return to standard study measurement schedule.
0289 BLISS	8-9	×	Weight decreased by 10g.	Extra measure at 10 months.	Weight increased by 170g between 9 and 10 months.	Satisfactory gain between 9 and 10 months; return to standard study measurement schedule.